# EXHIBIT 45

## ( Celsis | Analytical Services

Calala Laboratory Group will not begin work		The second secon			
SEND REPORT TO: Attention/		SEND INVO		no as report	Address below
Tala DM Spati	iNE	Attention: .			
Company: UDL LAGOR	entonies	Company:			
Address: 1718 Northro	ck Ct	Address:			
City. State, Rockfoco, H	9. 61103	City, State, Zip			
Phone 815-654-730	۷	CREDIT CA	RD: AMEX	☐ MASTERO	ARD [] VISA
ex 8/5-282-93	9/	Cardholder Address			
mail	· · · · · · · · · · · · · · · · · · ·	Name on Card			
**************************************		Card#:			Exp.:
Standard – 10 Business D Results Request: ☐FAX Repo (# no	ort Only FAX Repo	ort and Raw D	(Express i	is subject to pri	By: \( / \alpha \ / \D) or approval and availability and Mall Raw Data
aditional Information/Special Instr	ructions/Promotion Code:			Qu	ote Number: ch copy of quote ( appropriate)
01#: 611 00A1 (SEA +47)	130) 61 097A1 (SE)		Digital 125m 60992A1(SI	id#7 n	æ
ot#: (@[[ COAH (SE4 HP] ]  CAP ROSE  simple Date and Time (if applicable):  mutualled Substance   YES   DANO  fes: DEA # (REQUIRED):  AZARDS:   Antineoplasic   Caro  TEST(S) TO BE CONDUCTED	Top) 61 097Al (Stide Sample C	th 4 TOP	60 9 92 A-1 (\$1 Exp. 11/08 iner: Numb Schedule: (mark one)	per of Cantain	ers
of #:	Cytotoxic   Other Province   Other Pro	tr 4 TOA	E# - 11/08 iner: Numb Schedule: (mark one)	per of Cantain	ers
ot#:	Cop   Cop	tr 4 Top)  (uantity per Contain DEA pense)  DEA perse  DED)	Schedule: (mark one)  LIMIT (Specific (AS REQUIR	over of Contain    N	LABEL POTENCY (IF APPLICABLE)
of #:	Cytotoxic   Other Province   Other Pro	tr 4 TOA	Schedule: (mark one)  LIMIT (Specific (AS REQUIR	over of Contain    N	LABEL POTENCY (IF APPLICABLE)
ntrolled Substance TYES (INTO CARD):  TEST(S) TO BE CONDUCTED  (MUST BE PROVIDED)	Top) 61 097Al (St.)  Cap 12/08  Sample C	tr 4 Top)  (uantity per Contain DEA pense)  DEA perse  DED)	Schedule: (mark one)  LIMIT (Specific (AS REQUIR	over of Contain    N	List chemical  LABEL POTENCY (IF APPLICABLE)
TEST(S) TO BE CONDUCTED  (ALL COAL (SE4 147 1  CAP RIGG  (III applicable):  Introlled Substance   YES (DINO  (es: DEA # (REQUIRED):  ZARDS:   Antineoplasic   Carc  TEST(S) TO BE CONDUCTED  (MUST BE PROVIDED)	Copyright   Copy	tr 4 Top)  (uantity per Contain DEA pense)  DEA perse  DED)	Schedule: (mark one)  LIMIT (Specific (AS REQUIR	over of Contain    N	List chemical  LABEL POTENCY (IF APPLICABLE)
in #: (ell COAI (554 HT) 1  ZAP RIOS  Imple Date and Time (if applicable):  Introlled Substance   YES   PINO  fes: DEA # (REQUIRED):  ZARDS:   Antineoplasic   Caro  TEST(S) TO BE CONDUCTED  (MUST BE PROVIDED)  more than one Method is used	Copyright   Copy	tr 4 Top)  (uantity per Contain DEA pense)  DEA perse  DED)	## 11/08 iner: Numb Schedule: (mark one) □    □       □  LIMIT (Specifi (AS REQUIR  ### 90.0 ~ 11.0.  NUT Who in	per of Contain  N V  (cation)  RED)	List chemical  LABEL POTENCY (IF APPLICABLE)
ot#: (@[  COA  (SE4 HP) 7  ZAP 12/06  Imple Date and Time (if applicable):  Imple Substance   YES   DATO  fes: DEA # (REQUIRED):  ZARDS:   Antineoplasic   Caro  TEST(S) TO BE CONDUCTED  (MUST BE PROVIDED)  more than one Method is used	Copyright   Copy	tr 4 Top)  (uantity per Contain DEA pense)  DEA perse  DED)	## 11/08 iner: Numt Schedule: (mark one)                     LIMIT (Specifi (AS REQUIR  90.0 ~ [[0.	over of Contain  N V V  (cation)  RED)  30 1 min	List chemical  LABEL POTENCY (IF APPLICABLE)
ot#: (@[  COA  (SE4 HP) 7  ZAP 12/06  Imple Date and Time (if applicable):  Imple Substance   YES   DATO  fes: DEA # (REQUIRED):  ZARDS:   Antineoplasic   Caro  TEST(S) TO BE CONDUCTED  (MUST BE PROVIDED)  more than one Method is used	Copyright   Copy	tr 4 Top)  (uantity per Contain DEA pense)  DEA perse  DED)	## 11/08 iner: Numb Schedule: (mark one) □    □       □  LIMIT (Specifi (AS REQUIR  ### 90.0 ~ 11.0.  NUT Who in	over of Contain  N V V  (cation)  RED)  30 1 min	LABEL POTENCY (IF APPLICABLE)
ot#: (#! COAI (SEA 147) 7  ZAP 12/06  semple Date and Time (if applicable):  ontrolled Substance   YES   DATO  fes: DEA # (REQUIRED):  ZARDS:   Antineoplasic   Caro  TEST(S) TO BE CONDUCTED  (MUST BE PROVIDED)  more than one Method is used	Copyright   Copy	tr 4 Top)  (uantity per Contain DEA pense)  DEA perse  DED)	## 11/08 iner: Numt Schedule: (mark one)                     LIMIT (Specifi (AS REQUIR  90.0 ~ [[0.	over of Contain  N V V  (cation)  RED)  30 1 min	List chemical  LABEL POTENCY (IF APPLICABLE)
ot#:	Copyright   Copy	tr 4 Top)  (uantity per Contain DEA pense)  DEA perse  DED)	## 11/08 iner: Numt Schedule: (mark one)                     LIMIT (Specifi (AS REQUIR  90.0 ~ [[0.	over of Contain  N V V  (cation)  RED)  30 1 min	LABEL POTENCY
of #:	Copyright   Copy	tuantity per Contain DEA pense)	GO 9 92 A-1 (St E#- 11/08 iner:Numb Schedule: (mark one)                   LIMIT (Specifi (AS REQUIR  90.0 ~ 110.  NUT 85% in Goe the Ave of	per of Contain  N   V  (cation)  NED)  O %  30 Mm/s  (company)	List chemical  LABEL POTENCY (IF APPLICABLE)
ample Date and Time (if applicable): ontrolled Substance   YES   DANO Yes: DEA # (REQUIRED): AZARDS:   Antineoplastic   Carc TEST(S) TO BE CONDUCTED (MUST BE PROVIDED)  more than one Method is used	Copyright   Copy	tuantity per Contain DEA pense)	## 11/08 iner: Numt Schedule: (mark one)                     LIMIT (Specifi (AS REQUIR  90.0 ~ [[0.	per of Contain  N   V  (cation)  NED)  O %  30 Mm/s  (company)	LABEL POTENCY (IF APPLICABLE)
of #: GIL COAL (State 147)  CAP Table  ample Date and Time (if applicable):  ontrolled Substance   YES (BINO  Yes: DEA # (REQUIRED):  AZARDS:   Antineoplastic   Carc  TEST(S) TO BE CONDUCTED  (MUST BE PROVIDED)  more than one Method is used  ASBAY  Dissolution	Cap   Cap	tuantity per Contain DEA pense)	GO 9 92 A-1 (St E#- 11/08 iner:Numb Schedule: (mark one)                   LIMIT (Specifi (AS REQUIR  90.0 ~ 110.  NUT 85% in Goe the Ave of	per of Contain  N   V  (cation)  NED)  O %  30 Mm/s  (company)	LABEL POTENCY (IF APPLICABLE)

Page 4 of 5
Forms: CAD013.12 Effective Date 07/13/08



### Celsis | Analytical Services

Sample Name	Digitek 125 mcg (0.125) mg, 250 mcg (0.25) mg  Tablets
Method	Current USP Edition and all Supplements

Test Name	Method/Limit	Tavn Around Time (Days)	Price (8) per Sample
Digoxin Assay	Current USP Edition and all Supplements	3	\$1.575
Dissolution	Current USP Edition and all Supplements	3	\$3,810
	Secretary and a support of the secretary secretary and the secretary secreta	Total (1 Lots)	\$5,385
		Total (3 Lots)	\$16,155
	Total	(20% Replicate)	\$12,925

NOTES: There will be an additional charge for GLP guidelines. Any additional work outside of this project quotes will be additional and will charged at an hourly rate established in advance of the work taking place. This quote is subject to the terms listed in the Contract for Analytical Services.



Chuck Koon/MGW/MYLAN 01/26/2007 02:17 PM

To Li Radike/RCKFRD/MYLAN@MYLAN

CC Patricia Latzo/MGW/MYLAN@MYLAN

bcc

Subject Digitek Samples for Testing

This is the data for the three lots (1 bottle each) that are being FedEx'd to you today for receipt Monday. Please send a cover letter from UDL requesting the testing.

Just to recap, please don't send any of the blistered samples.

I appreciate all of your efforts and the request for Celsis to expedite the testing and results.

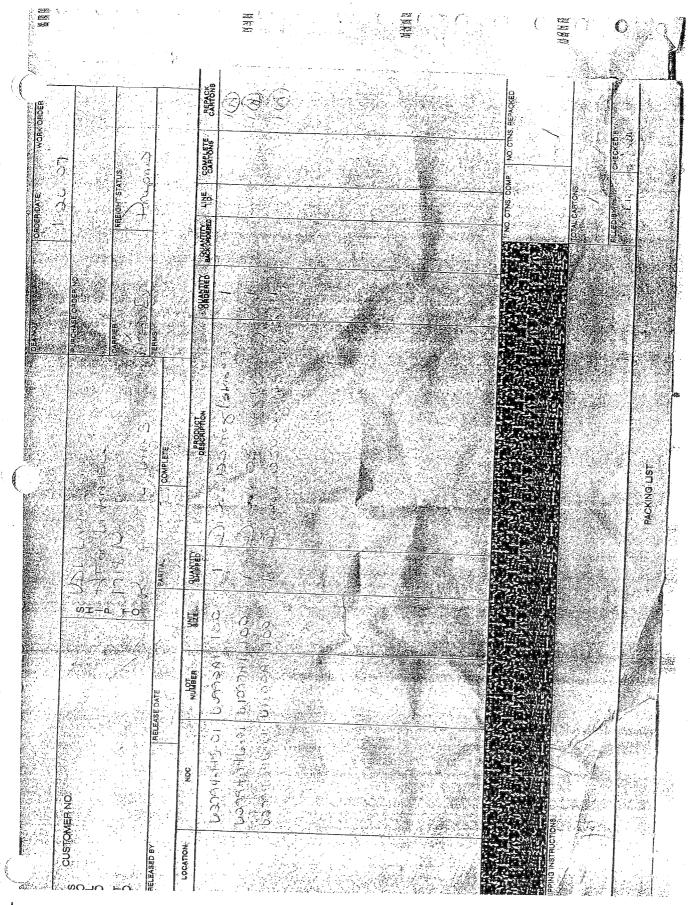
Please let me know if you have any questions or need anything at all.

Thanks,

Chuck

NDC	PRODUCT	LOT	EXP
62794-145-01	Digitek125mcg	60992A1	11/08
62794-146-01	Digitek 250mcg	61097A1	12/08
62794-146-01	Digitek 250mcg	61100A1	12/08

Charles E. Koon, Director, Quality Assurance Mylan Pharmaceuticals, Inc. 781 Chestnut Ridge Road Morgantown, WV 26505-4310 (304) 598-5430 ext, 6167



#### UDL LABORATORIES, INC.

1718 Northrock Court, Rockford, IL 61103 (815) 282-1201 FAX (815) 282-9391

#### TRANSMITTAL FORM FOR PRODUCT

**DATE: January 29, 2007** 

TRANSMITTAL NO.: A29A3

FROM:

TO:

UDL Laboratories, Inc. 1718 Northrock Court Rockford, IL 61103 Celsis Laboratory Group 6200 S. Lindbergh Blvd. St. Louis, MO 63123

Attn: JoAnne Sidwell

DEA #: PU0219902

DEA #: N/A

Quantity Sent	Product Sent	UDL Lot	Vendor	Vendor Lot
1 Bottle of 100 100 Tablets	Digitek (digoxin tablets, USP) 125 mcg (0.125 mg)	N/A	Actavis (Amide)	60992A1
	Exp. 11/08			
1 Bottle of 100 100 Tablets	Digitek (digoxin tablets, USP) 250 mcg (0.25 mg)	N/A	Actavis (Amide)	61100A1
	Exp. 12/08			
1 Bottle of 100 100 Tablets	Digitek (digoxin tablets, USP) 250 mcg (0.25 mg)	N/A	Actavis (Amide)	61097A1

Note: Test all samples for Assay and Dissolution per current USP and Supplements. See attached Analytical Services Contract and Quote.

SIGNATURE
DATE SHIPPEDPage <u>1</u> of <u>1</u>

Exp. 12/08



UDL LABORATORIES, INC.

1718 Northrock Court, Rockford, IL 61103 (815) 282-1201 FAX (815) 282-9391

#### FAX MACHINE COVER SHEET

•		
DATE_2/2/07	NUMBER (	OF PAGES (INCLUDING COVER)
TO WHOM SENT Chuck	Koon	
COMPANY NAME Mylon		
FAX# 304-554-6329 FROM T-SpainE		PHONE #
FROM T-SPAINE		
COMMENTS_		
Digital	DATA.	
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#### IMPORTANT CONFIDENTIALITY NOTICE

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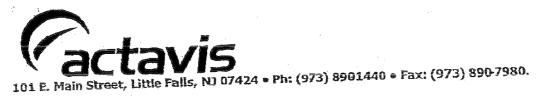
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JAN. 29. 2007 11:56AM

MYLAN GSO QA

NO. 5006 P. 2



Digoxin Tablets, 0.25 mg

BATCH # 61100A

#### CERTIFICATE OF ANALYSIS GENERATED FOR CUSTOMER PURPOSES ONLY

All testing has been performed in accordance with GMP and GLP and all results have been found to comply with the registered specifications.

Part of Bulk Batch # 61100A is bottled as Control # 61100Al (PACK SIZE 100)

Manufactured Date: 12/20/06

Approved By: Balance Regulatory Affairs

Date:

1/18/2007

יח ום לחמל ליח בי חים

JAN. 29. 2007 11:56AM

MYLAN GSO QA

NO. 5006 P.

Actavis Totowa LLC

#### CERTIFICATE OF ANALYSIS

Product Name: Digoxin Tablets, 0.25 mg

Date of Analysis: 01/11/07 Control No: 61100A Exp. Date: December 2008

Test	RESULT	LIMIT
DESCRIPTION: Color:	White	White
Profile:	Round bisected tablets	Round bisected tablets
Other: Debossed	"B 146" on bisected side	"B 146" on bisected side
FRIABILITY:	0.2%	NMT 1.0%
IDENTIFICATION: (A)	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.
(B)	The Rf value of test solution corresponds to standard solution.	The Rf value of test solution corresponds to standard solution.
ASSAY:		
Digoxin, 0.25 mg	99.5%	90.0% - 105.0%
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity) Digoxin, 0.25 mg	1) 98.9% 6) 98.8% 2) 99.7% 7) 98.8% 3) 100.2% 8) 99.5% 4) 100.6% 9) 97.7% 5) 98.9% 10) 98.9%	85.0% - 115.0% RSD: NMT 6.0%
	Average: 99.2% SD: 0.83%	
DISSOLUTION: Media: 500mL; 0.1N HCl Apparatus: 1, RPM: 120 Temp: 37.0°C ± 0.5°C Time: 60 minutes	1) 102.0% 4) 100.7% 2) 96.6% 5) 102.7% 3) 98.0% 6) 96.9% Average: 99.5%	NLT 80 % (Q) of the labeled amount of Digoxin is dissolved in 60 minutes.
Related Substances; Digoxigenin	0.265%	NMT 2.0%
Digoxigenin bisdigitoxoside	Not detected	NMT 2.0%
Gitoxin	Not detected	NMT 3.0%

Director of Quality Control

01/18/07 Date

ບຸງ ຂວາດ ເປນລະເສດ

V1/ 2007 11.02 FAA 314 487 8778

CELSIS LABS

@001

### Celsis | Analytical Services

### Report of Analysis

Attn. Name: Company: Address:

Thomas Spaine

UDL Laboratories, Inc

1718 Northrock Court

City, State, Zip: Rockford, IL 61103

Sample ID#: 783542 Report Date:

02/01/2007 01/30/2007

Received: Department: Chemistry

Page:

1 of 1

Sample: Digitek 250 mcg

Lot #: 61100A1 (Skid #7 Top) exp 12/08

Digoxin Assay

Method:Current USP and Supplements Claim: 250 mcg/tablet 0.250 mg/tablet

Limit: 90.0 - 110.0%

Result: Date Assayed: 1/30/2007

249 mcg/tablet (99.6%)Conforms

Dissolution

Method:Current USP and Supplements Claim: 250 mcg/tablet 0.250 mg/tablet

Limit: NLT 85% in 60 min for the avg of the tablets tested

Result: Date Assayed: 1/30/2007

Component: Digitex

Stag	e 1 Results
Sample #	% Dissolution
1	94
2	98
3	97
4	97
5	. 99
6	94
Average for 6	97

Conforms

Unless alternate arrangements have been made, sample will be retained for 30 days and raw data for 7 years after report date

Celsis Laboratory Group 6200 S. Lindbergh Blvd. St Louis, MO 63123 USA T+1 314 487 6776 F+1 314 487 8991 Celsis Analytical Sarvices represents that this is a confidential report which may be used when requested by physician and health officials,

but is not to be used in any form of advertising without written permission Part of the Celsis International plc group of companies www.celsis.com

24-1-45 SL

02/01/2007 17:02 FAX 314 4	S7 6776 CELSIS LABS	Ø 002
IDL Laboratories, Inc	Due: 02/02/2007	Sample ID#: 783542
Sample: Digitek 250 mcg PO #: A29A3	Lot #: 61100A1 (Skid #7 Top) exp Dese: white plastic bottle  Qty: 1 bottle 100 tablets	12/08 Page: 1 of 5 Extra: NA
Safety Name: No Safety Type DEA #: N/A	Corrections:	Log: 01/30/2007
Instructions: For all disintentations reports	niber of minutes, when possible. Send all data and reports over	To 21 lister
Digoxin Assay Current USP and Supplements	Results:	51,575,00
Claim: 250 mcg/tablet 0.250 mg/table	/=1	
Limit: 90.0 - 110.0% SubDept: HPLC	(99.62) (99.6	
Alert Limits: 93.37 106.77	<u> </u>	does not
Anc Data: Yes No Anc Ref:	31282 - 24m3 Assay Date:	
Method Instructions: NA	20110	1/30/07
(Bal 19) Spl Prep 481.6 mg transferred 3:13007 × 37.00	to 2 glass-stoppered, 5 (diluted successed) with sw	295 glear tab x 1000 mg/g  = 120, 295 mg/tab  x Img = 481.18 mg g spl needed  50-ml conical flask, added virting. Sonicated (50N-2)  Filtered = portion through carded first 10 ml g
Assay Result: 0.2	489 mg/mt × (1000 mg/m mg/mt × 100% = 99.56 mg/mt 99.6	20/2 21/20 ( )

I'my balance AEB 1/20/07 (Dwg zent 21/107 AOB (	Dunits Acts alon (Darcidental line-out Acts 2/1/07
Signature/Date: Rischoff 2/1/07	Reviewed By Date:
Figure SCH007.10 Filterlye: 10-17-2003 Foge 1 of 2	Reviewed By/Date: Chais Vauga Z/11/07
Page 1 of 2	$\mathcal{O}$

01/30/2007 14:56:57

101 EAST 12:07 1:17 ALA 401	OTTO CELSIS LABS	Q 003
	<b>Due:</b> 2/2/2007	Sample <b>ID</b> #: 783542
SubDepartment: HPLC	ANL #:	
	1	98 Extra: NA
		Chromeleon Pages: NA
Analyte:		ID# Reference
Method:		(81282-
System Identification:	7	24m0
Column:		
Mobile Phase:		NA Au
		NI NES
		1 / 1.1/2
		1 / 2/16
Wavelength/Inj. Volume/Flow Rate	:	
Standard Data		1/
•		'
. /		
NA	AEB of Adhress	alter a 1.0
///		d to : <u>NA</u>
1 211	C <sup>-</sup> ( with	N A (pH adjusting solution)
	on pH Mete	r#NA_orpHT#_NA
/ see v	281282-24m0 pH Buffer C	heck(s) (pH tester)
Signature/date: R: TH		
JOSCHOLD SCHOOL	2/1/07 Reviewed by/date: Ch	55 Vivaly 2/1/07
Form: SCH007.10 Effective: 10-17-2003	2/1/07 Reviewed by/date:/h	55 Vivolin 2/107

01/30/2007 14:56:57

CELSIS LABS

02/01/2001 11:00 FAA 014 487 6776

02/01/200/ 17:03 FAX 316	487 6776 CELSIS	LABS	@ 004
	,		
	Interval: 24 Month	Due: 2/12/2007	Sample ID#: R81282
Sample: Digitek (Digoxin)		c Amide/Berrek Vondor# 4277A	ANL#:
125 mcg (0.125 mg) Tab	ets. USP Desc: UVI Package	<b>2</b> '	498
Date: 1/29/07	SubDepartment; HPLC		Page: 4 of 7 Extra: Affil 44
Segveno	the orange	Chromeleon	
O	#'S 013107-498-1 013107-498-12	(for system suit)	ANCILLARY
Analyte: Digox	in (Digitek) table	45	ID# Reference
<u>~</u>	OL 29 (diacxir		C81282-24m
System Identification: L		and the order of the control of the	783547
	ð		183543
	18 54 120A 25cm x 4.2	,	* 1
	ic C18 Su 3/N: 23704-		
`	H20: ACN) 2220		0
(Building B) -	- 780 mz ACN (	(Fisher, Optima)	NA NA
104 phototi gexp	orlos). Filtered	and dearsed	AUS
· · · · · · · · · · · · · · · · · · ·	NA	3	1307
Wavelength/Inj, Volume/Flo	w Rate: 218-nm / 5	Oul / 3.0 mL/m	in /
Standard Deta			
Billyed Alcohol +	500-me Ethyl Alcoho	(AAPER, 04 DZOQA	A, OHOA)
2	ng wixeg bounded more	5 (B-12) to 2 100	CO.Oml flask, mike
(BZ) 210) (See P.	dried at 105°C x 1 now	K. BashpH Adjusted to: N	IA
4.110mg - 0.060mg =	4.050mg > 100.0-mL	with	
Dig. Purity Factor = 0,961.	ns/mg for RS		usling solution)
System Suitability A	'eo !	on pH Meter# N	↑ or pHT# NA (pH tester)
(521 201 4.041mg - 0.00	13 mg USP Digonth RSD	pH Buffer Check(s)	
4.041mg-0.008mg - 4	1.033 mg (USP Digoxin RS).		
2015mg-0.01eng -	1.009 mg (Digoxigenia)	, , , , , , , , , , , , , , , , , , , ,	(lonalis batuli
pried std in Vacuum O	en I (T-266) It 25 Th	Ag x 1 hr/TM-Ti	) at 107°C for Deviction
(3) Reprepped System :	suitability Prop because suitability. See pe	use integration of 4 4A for reprep.	Digoxin RS was
O spelling AEB 1/28/07 (	Predried std AER 1/20107	PHORDING ABB ITAIN	W-4
Signature/date: Bisc	to/ 1/31/07 Reviewed	d by/date: // \/ ()	_ Z   07
Form: SCH007,10 Effective: 10-17-2003 Page 2 of 2		0	

01/26/2007 14:25:50

U2/U1/2007 17:03 FAX 314 487	6776 CELSIS LA	BS		@005
	•			
	Interval: 24 Month	Due: 2/12/2007	Sample ID#:	D 9 1 2 0 2
Sub Dept: HPLC		ANL #:	vangic ii#:	
			·	Page: 4 /
		448		MANIA. NI
System Scitability Rep (Bal Zle) 4.124mg - 0.014mg = (Bal Zle) 4.119mg - 0.022mg:	Additional Analyst Geo: 4.110mg(USP Digoxinn =4.097mg(Digoxygenin		L (diluted a	ucchol)
Std concentration:			ID # REFE	
SIG CHEET WARDIN	4.050mg = 0.04	re mal.		- 1
	100.0ML	-) SIML		VEB 1/21/01
			783542	
			R81282-24m	0 /
			NA NA	
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Signature/Date: Risdoff	2/1/07 Revi	ewed By/Date: //	- : A	
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1/31/2007 10:57:22AM

CHIPSONT SEE	OSCINO HUMANIA	distribution of the last of th		****								
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J Sec. 1	011	201	,,		. U	-0	F ALA	-3 (	41 /		/ K/	7 6

CELSIS LABS

Ø 006

·		Ch	romatography	Report		
	uence Title:	Digoxin Assay	- Ding	ITCPUIL	Total Co.	
, .	uence Name:	013107-498-1a			Total Samples	: 15
	tem ID:	LC-22			Sample No.:	11
Proc	essing Date/Time:	02/01/07 08:58:43				
Cres	ited by:	Anna Bischoff				
-	ation:	ServerData	2007\1 JAN THRU	MADCLAGO		
Cali	bration	*		INATIONAS		
No.	Peak Name		Cal.Mode	Cal.Type	#Polnts	Corr.Coeff.
Peal	Analysis					<u>%</u>
No.	Peak Name		Resolution (USP)	Tailing	Plates	K
Syst	em Suitability		<u> </u>	·	(USP)	AND ASSESSMENT OF THE PARTY OF
	T.		n.s.	n.a.	n.a.	n.a.
No.	Name		UV VIS 1	UV VIS 1	UV VIS 1	UV VIS 1
7	Standard 1		n.a.	7.99629765	n.a.	n.a.
	Standard 2		n.a.	8.00257021	n.a.	n.a.
14	Standard 3	0/808	n.a.	7.79733928	na na	n a
··········	L	%ASD	#DIV/0I	1472	#DIV/0I	#DIV/BI
	st Signature/Date:	Anna Bisci Chemis	hoff		ANC	ILLARY
QC R	eview/Date: _	Chris lange	2/1/07	<del></del>		

6.70 SP2a Build 1871 Version Number 2.2 added p. 1A to show system scitzbility
Page 1 of 16

ABB CUTTEN CATEGORY
CUTTEN CHIEFE 11 AM

Confidential Subject to Protective Order

UDLL 000011692

2/01/2007 17:03 FAX 314 487 6776

CELSIS LABS

@007

Chromatography Report

Sequence Title: Sequence Name:

Digoxin Assay 013107-498-1

Total Samples: 15

System ID:

LC-22

Sample No.: 2

Processing Date/Time: 02/01/07 08:58:21

Created by:

Anna Bischoff

Location:

ServerData

2007/1 JAN THRU MARCH/498

-aiii	acion
No.	Peak !

l No.	Peak Name	1			
g . 40.	i edvidilie	Cal.Mode	Cal.Type	#Points	Corr.Coeff.
1					%
	Digoxygenin	Total	Lin .	E	99.978
2	Digoxin	Total			
Peak	Analysis	L IVIAI	Lin I	5	99.833
The same of the same of					
No	Dook Name				

Same was			•		
No.	Peak Name	Resolution	Tailing	Plates	ĸ 1
-	Digoxygenin	(USP)		(USP)	
+	Diocxin	20.09	2.69	2171	n.a.
Suce	Establish Slide	n.a.	1.59	3192	n.a.

System	Suitability
--------	-------------

		Digoxygenin	Digoxin	n.a.	n.a.
No.	Name				
2		UV VIS 1	UV VIS 1	UV VIS 1	UV VIS 1
<del></del> _	System Suitabilly 1	21.24568128	7.97854416	n.a.	The second secon
3	System Suitability 2	21,24225169	8.00342777	-	n.a.
4	System Sultability 3	21,61113648	8.24638881		<u>n,a.</u>
5	System Suitability 4	- Commence of the Commence of			n.a.
6	System Suitability 5	21.64084213	8.26660165	n.a.	n.a.
		21,65278587	8.18960910	n,a,	na
	%R\$D	0 999	1.577	#DIV/0!	#DIV/01

Analyst Signature/Date:

ANCILLARY

QC Review/Date:

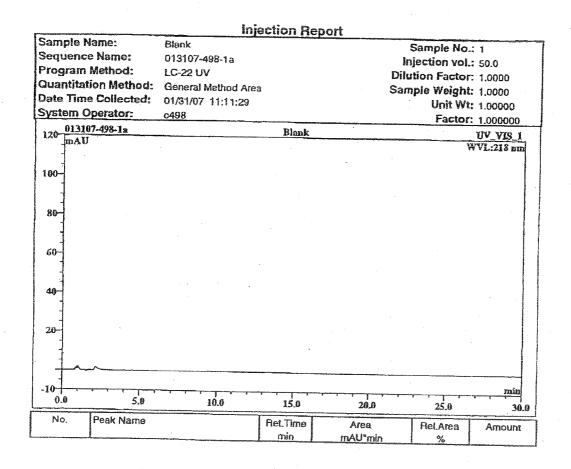
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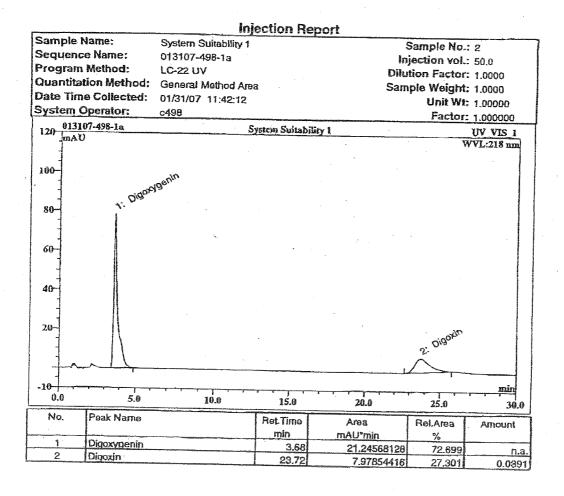
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Page 2 of 16

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Chris Vargan 2/1/07

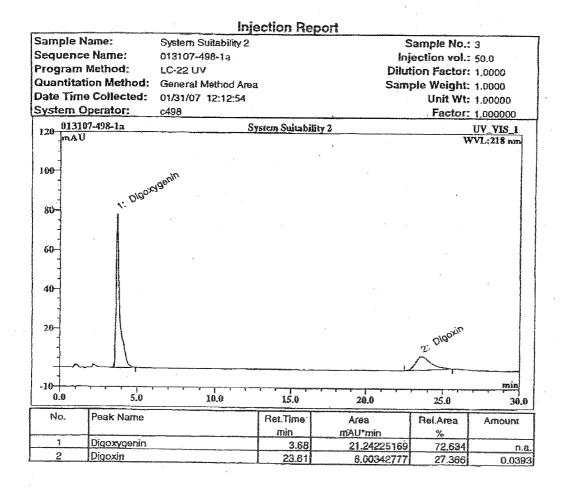
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Page 3 of 16

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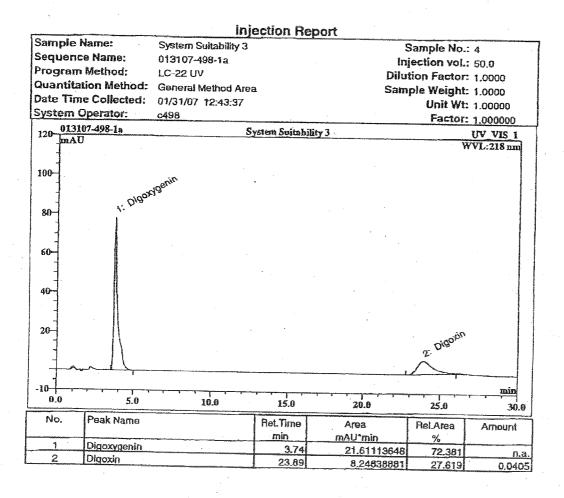
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Page 4 of 16

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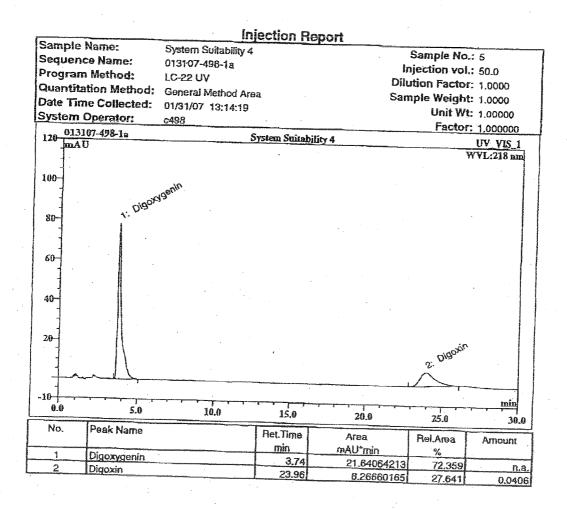
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Page 5 of 16

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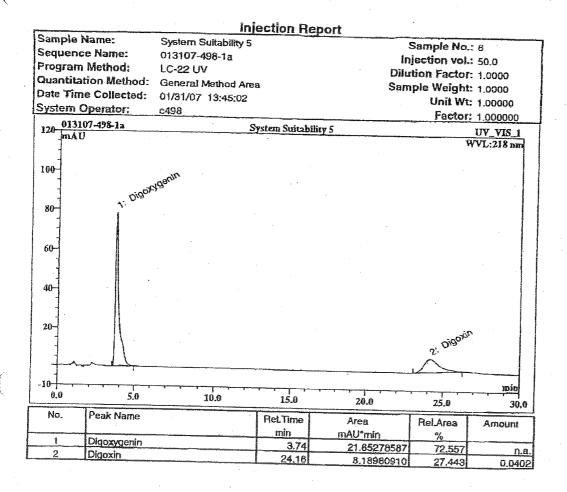
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6.70 SP2a Bulld 1871 Version Number 2.2

Page 6 of 16

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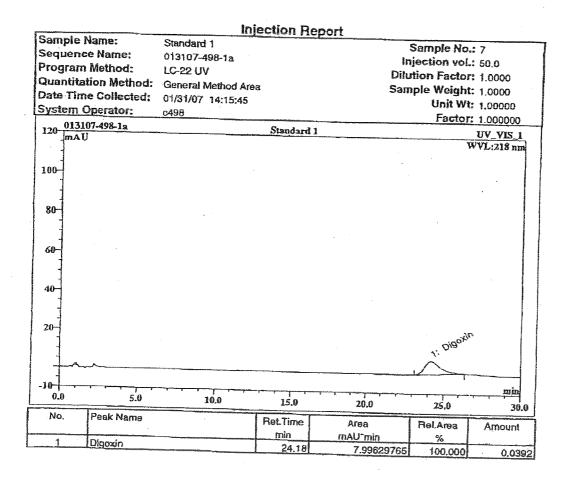
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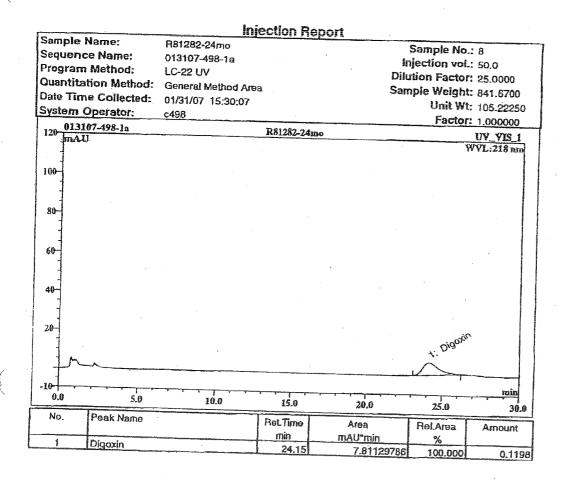
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Page 8 of 16

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CELSIS LABS

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ChrisVargh

6.70 SP2a Build 1871 Version Number 2.2

Page 9 of 16

**Injection Report** Sample Name: 783542 Sample No.: 9 Sequence Name: 013107-496-1a Injection vol.: 50.0 Program Method: LC-22 UV Dilution Factor: 1 0000 Quantitation Method: General Method Area Sample Weight: 1.0000 Date Time Collected: 01/31/07 16:00:13 Unit Wt: 1.00000 System Operator: Factor: 1.000000 013107-498-1a 783542 Can't open raw data file "\CELSISSQL02\RawData\$\2007\1 JAN THRU MARCH\1998\ UV\_VIS\_I 013107\_498-1a.SEQ\UV\_VIS\_1.CHL\9.acd". The system cannot find the file specified. n.a. n.a. n.a.

Vial missing. Nothing injected into system.

ACB 41/07

ANCILLARY

Christangen 2/1/07

6.70 SP2a Build 1871 Version Number 2.2

Page 10 of 16

силет date:2/1/2007 cutrent time: 9:11 AM 70172007 17:03 FAA 314 487 6776

CELSIS LABS

@017

Injection Report Sample Name: 783543 Sample No.: 10 Sequence Name: 013107-498-1a Injection vol.: 50.0 Program Method: LC-22 UV Dilution Factor: 1.0000 Quantitation Method: General Method Area Sample Weight: 1,0000 Date Time Collected: 01/31/07 16:00:27 Unit Wt: 1.00000 System Operator: Factor: 1,000000 013107-498-12 783543 UV\_VIS\_1 Can't open raw data file "\CELSISSQL02\RawData\$\,2007\1 JAN THRU MARCH\498\ 013107-498-1a.SEQ\UV\_VIS\_1.CHL\10.acd". The system cannot find the file specified. n.a. n.a. n.a. n.a. n.a. n.a. n.a n.a.

Vizd missing. Nothing injected into system
AEB 24/07

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6.70 SP2a Build 1871 Version Number 2.2

Page 11 of 16

CELSIS LABS

2/01/2007 17:08 FAX 314 487 6776

**Injection Report** Sample Name: 782544 Sample No.: 11 Sequence Name: 013107-498-1a Injection vol.: 50.0 Program Method: LC-22 UV Dilution Factor: 1.0000 Quantitation Method: General Method Area Sample Weight: 1.0000 Date Time Collected: 01/31/07 16:00:45 Unit Wt: 1.00000 System Operator: Factor: 1.000000 013107-498-1 782544 UV\_VIS\_I Can't open raw data file "NCELSISSQLOZ/RawData\$/2007/1 JAN THRU MARCH/198/ 013107-498-1a\_SEQ\UV\_VIS\_1.CHL\11.acd". The system cannot find the file specified.

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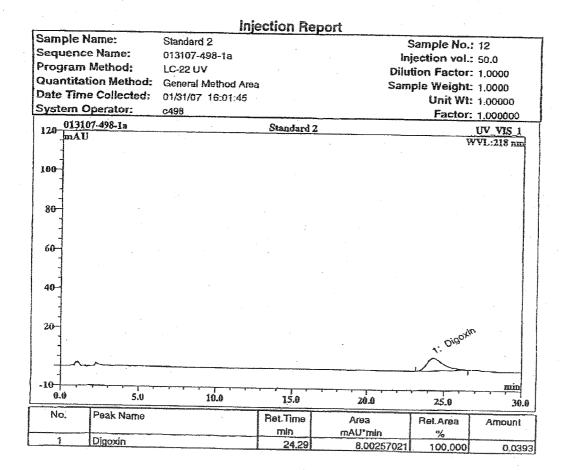
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Page 12 of 16

current date:2/1/2007 current time: 9:11 AM

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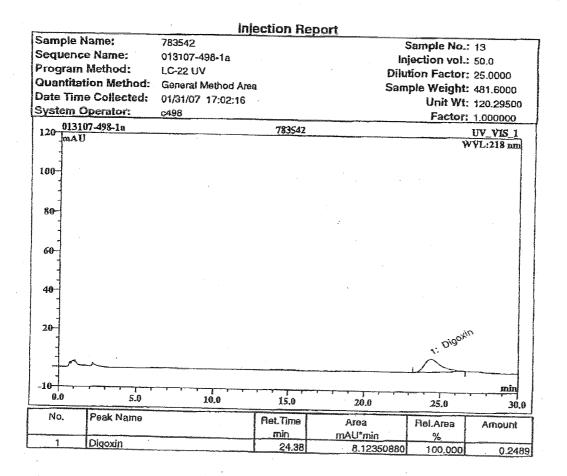
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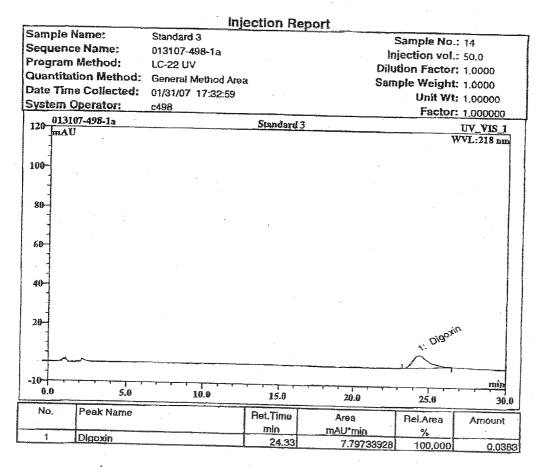
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6.70 SP2a Build 1871 Version Number 2.2

Page 14 of 16

1



This value not used in calculation of Spi prep. AEB 2/1/07

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Chris Vargan 2/1/07

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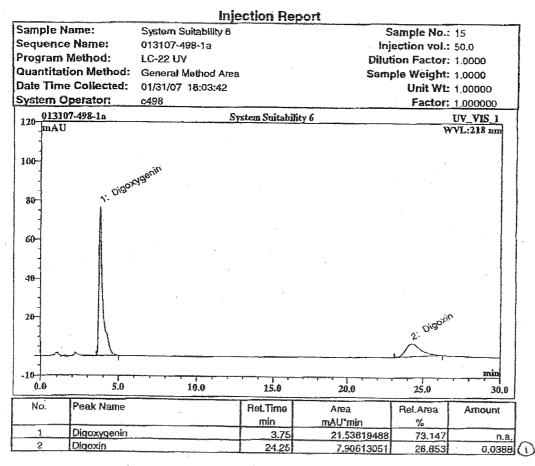
Page 15 of 16

current time: 9:11 AM

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CELSIS LABS

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ANCILLARY

The digorin zund was calculated as a "sample".

See P. 14 A for system suitability value. This value not used in any calculation. Arms 21/07

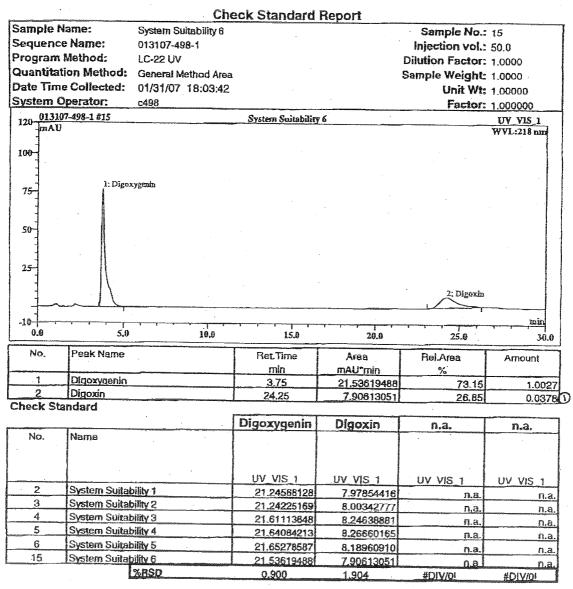
Chustage 2/1/07

added p. HeA to show system suitability ASB 4/07

6.70 SP2a Build 1871 Version Number 2.2

Page 16 of 16

сителі date:2/1/2007 current lime: 9:11 AM



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Dant of digoxin std calcid as standard to show system suitability over enthe run. LOB 24107

p. 11eA added page
Page Total AEB 2/1/07
Chioleogue 2/1/07
Chioleogue 2/1/07

6.70 SP2a Build 1871 Version Number 2.2

CELSIS LABS 0024 UDL Laboratories, Inc. Due: 02/02/2007 Sample ID#: 783542 Sample: Digitex Lot #: 61100A1 (Skid #7 Top) exp 12/08 Page: 3 of 5 250 mcg Desc: white plastic bottle Extra: N/A PO#: A29A3 Qty: 1 bottle 100 tablets Log: 01/30/2007 Corrections: M HILL BY Safety Name: No Safety Type 9 NLT 85% 60 min . 20 % loc DEA #: N/A Instructions: For all disintegrations report number of minutes, when possible. Send all data and reports overnight Results: \$0.00 Current USP and Supplements 0.00 % \$3,810.00 Claim: 250 mcg/tablet 0.250 mg/tablet See Below 480 Limit NLT 50% in 30 min and NLT 85% in conforms SubDept: Dissolution does not Alert Limits: NA NA Anc Ref: 783542 Anc Data: (Yes) No Assay Date: 01-30-07 Method Instructions: Osec Client E-mail for Limit - 01-31-07/My Ong.info. 01-31-07-My Stage 1 Results USP-29 ONLINE (DIGOXIN) Sample No. % Dissolution 94 % Dissolution (x) 2 Response(4) 98 19.362228 3 1.0 ml 124 97 4 38-724456 97 2.0 ml 271 58.086684 5 99 3.0 mL 412 77.448912 6 4-0 mL 581 94 97 96-81114 732 Average for 6 5.0 mL FACTOR -5.037 no x 10.0 mL x 500mL x 1.0mL x 0.961mg x 100 FACTOR - 19362228 CORR. COEF = 0.999574279 Sample % Dissolution from STD Curve. Reviewed by/date: Chus Vaus 101-31-07 Form: SCH004.8 Effective: 08-09-2002 Page 1 of 3

01/30/2007 11:08:55

	CELSIS LAB	5		@ 025
	Th. 040/0000		,	TT !!
Cub Danas de Cara Discolución	Due: 2/2/2007		Sample	<b>ID#:</b> 783542
SubDepartment: Dissolution		ANL#:	n	Page: 4 of 5
01-30-07	- Annual Control of the Control of t			Extra: W/A
Checklist Procedu	res for USP Apparate	IS (I) OR II	(circle one)	
Apparatus ID#: Volume:	500 mL Time	: 60 min T	imer#: Tm-5	4_
Medium: 0.1 N HCl				
58 ml HCI (Fisher, Lot # 0605		Heated	arobed pung	
pH: (IF APPLICABLE): pH Tester ID:	N/A			
pH: (IF APPLICABLE): pH Tester ID:  Buffer Set Value:	N/A Check V	alue: N/A	Media Value	: N/A
Buffer Manufacturer,	Lot# and Expiration D	ate:	N/A	
Inspect all paddles or baskets, shafts and check the verticality shaft.	, and vessels for clear Pa	nliness, deformati ass ⇒	ons, burrs, or oth	er defects,
2. Check the adjustment of each assem	bly so that each padd	e or basket is		
2.5 cm or 4.5 cm (circl	le one) HG-1			
above the inner floor of the vessel. T to the correct height. All are within to	he tolerance is 2 mm. lerance Pa	Each shaft is ma	arked so it can be	returned
<ol> <li>Measure temperature of the water ba</li> </ol>	th. The tolerance is 3	7° ± 0.5°C. F	°ass ⇒	
Temperature: 37.0	°C Th	emometer #:	NT-52	
<ol> <li>Select the gear drive or adjust the spe Turn on the motor drive. Measure the counting device. Allow the machine deviation from the speed specified in method is ± 2 rpm.</li> </ol>	shaft resolutions per to run for the time s	minute by manua	il count or his a ra	unlistina
Speed (rpm): 120.00 RPM	1			
<ol> <li>Inspect the shafts for straightness, wobble by placing a runout gauge as (0.04 in.).</li> </ol>	James Pach Sudit last	notor, engage clu above the paddio	utches, and meas or basket. The	sure the amount of tolerance is 1 mm
Wobble Gauge ID: WG-4	· · · · · · · · · · · · · · · · · · ·			
1. 0.006 2. 0.003	3. <u>0.004</u> 4	. 0.006	5. <u>0, 0 0 4</u>	6. 0.003
6. Measure the temperature of the media. Thermometer #: <u>bT-52</u>	ım în each dissolution	vessel. The toler	rance is 37° ± 0.5°	°C.
1 37.1°C 2 37.1°C	3. 37.2°C 4	. 37-1°C	5. 37-2 °C	6. 37.2 c
Signature/Date: Huuth /01-31-	-07 Revie	wed By/Date:	his Va. D	1/31/07
Form: SCH004.8 Effective: 08-09-2002 Page 2 of 3	And Pathing Control		X.	101101

01/30/2007 11:08:55

CELSIS LABS

SubDepartment: Dissolution		Sample ID#: 783542
	ANL#: 480	Page: 5 of 5
01-30-07	100	Extra: 5A - 5
STD reading is not Linear STD p was OFF Peprop all solutions. Addition	nal Analytical Worksheet	•
-31-07/my mw 2/1/07 Addition	151 75 IBI ATICAL TO KSTICKE	
OTZ-920) NIXODIA = DARDNATE	Lot # 008096, 0.961 mg/1	er ma)
SEE R81282 24 m	o. STD Drying and Sto	ck std.
	<b>3 3</b>	
WORKING ETD =		
10.0 ml STOCK STD -	50-0 -1 1 1 15 ALCOHOL	
Glossware rinsed with HCl	(Fisher, Lot # 060506, 10-09,	12.1 N) DI Water
and Alcohol (Aaper, Lot + 04L16	(68, 3-10) and corefully d	ried
	f	
4 IN 5 ALCOHOL		
160 ml Ethyl Alcohol (Ada	per. Lot # OUL16GB 370).	200.0 ml Han
ASCORBIC ACID - METHANOL SOLU		, 2.00
	manage and from the same of th	100
	Acid Sigma, 063K1082, 8-	· · · · ·
	(80-1, 3H12200 (angiz)	MEthano
HYDROGEN PEROXIDE - METHANOL	= NOITUJO2	
STOCK 20 at 4 days	. P (a)	1
100.0 ml moth	n Peroxide (Sigma, 095×3774, and (Sigma, 005×14E, 1-1	,3-07)
The Third the Th	en Peroxide Stock 100.1	Uml Methanol
= 2MOITUJOS DARDARTZ		
		\
1.0 ml (20%), 2.0 ml (40%), 3.0	ml (60 %), 4.0 ml (80%),	50 ml (100 %)
- 100.0 mL MEDIUM.		
		- And the state of
1 TABLET		
1 TABLET -> 500 mL M		
rittered with	0.45 micros Nylon filter.	
Signature/Date: Howelf 101-31-07	Reviewed By/Date: // . \/	7
		حاراه کا

01/30/2007 11:08:55

@ 026

UDL Laboratories, Inc. Due: 2/2/2007 Sample ID#: 783542 Sub Dept: Dissolution ANL#: 5 A docent need. 480 01-30-07

Additional Analytical Worksheet [Re-prop all solutions at 01-31-07 (see page 5B), used some Stock Diss. samples, and followed some procedure below and Read in Frazil

Propared 1.0 ml Medium as Blank, 1.0 ml each Standard

1.0 ml Medium as Blank, 1.0 ml each Standard

Solutions and 1.0 ml each Sample Solutions.

(wed PPT-7) Added Ascorbic Acid-Methanol Solution and swilled. 1.0 mL 5.0 mL HCl (Fisher, Lot # 060506, 10-09) and swilled. Added Hydrogen Peroxide - Methanol Working Solution Added 1.0 mL

and swirled than capped and allowed to sit 2 hours, Tm-54

FMR-I GAIN = 1000 SPAN = MAX

Fluorescence = 485 nm Excitation wouldingth = 372 nm. Excitation Filter = NB360 Emission Filter = SC415

zcroec	with	Blank	Duplication	Average	
272	20%	125	123	124	
STD	40%	274	268	271	
<u>672</u>	60%	409	414	412	
STD	80%	576	585	581	
STD	100 %	739	724	732	

	T	Duplication	Average
Sample VI	696	713	705
Sample V2	734	736	735
Sample V3	733	729	731
Sample VII	737	726	732
Sample V5	742	748	745
Sample V6	709	707	708
STB 100 %	724	728	726

ANCILLARY = 783544

1			
1	Signature/Date: /////		
ł	Signature/Date: Muntilly (CI-31-07	Reviewed By/Date: Chris Vander 2/1 07	
,	- JI VI	I worked by bace: / h. b. / /	
		- Markey 211101	
		The state of the s	
	Form#: SCHC001 4		
	Eff≪rive: 04-02-2004		
ı	Page I of 1		

1/30/2007 11:11:17AM

02/01/200/ 1/:08 FAX 314 487 6776

CELSIS LABS

Ø 028

UDL Laboratories, Inc	Due: 2/2/2007	Sample ID#:	783542
Sub Dept: Dissolution	ANI. #:	Page:	5 B
01-31-07		480	N/A

#### Additional Analytical Worksheet

STANDARD = bigoxin (usp-STD, Lot = 008096, 0.961 mg/pcr mg)

SEE R81282 24 mo. for STB drying and Stock STB.

(Page 4 of 7)

STOCK = Bal = 26 5.065 mg - 0.028 mg = 5.037 mg STD = 100.0 mL 41N 5 ALCOHOL

WORKING = 10.0 mL STOCK STD - 50.0 mL 4 IN 5 ALCOHOL

4 IN 5 ALCOHOL = 160 mL Ethyl Alcohol (Agrer, Lot # 041668, 3-10) -, 200.0 ml H20

ASCORBIC ACID - METHANOL SOLUTION =

Bal=19 200.00 mg Ascorbic Acid (Sigma, 063 K1082, 8-10) -- 100.0 ml Methanol (Sigma, 00561HE, 1-08)

HYDROGEN PERCXIDE - METHANOL SOLUTION =

STOCK = 2.0 mL Hydrogen Peròxide (Sigma, 095K3774,5-07) -, 100.0 mL Methanol (Sigma, 00561HE, 1-08)
WORKING = 2.0 mL H202- Methanol Stock -, 100.0 ml Methanol

STANDARD SOLUTIONS -

1.0 ml (20%), 2.0 ml (40%), 3,0 ml (60%), 40 ml (80%), 5.0 ml (100.0 %)
100.0 ml MEDIUM.

See page 5A to fallow FMRI reading and prep.

N/A 01-31-07 MY

Signature/Date: Whomes /01-31-07 Reviewed By/Date: Chris/aval 1/31/07

Form#: SCHC001.4 Effective: 04-02-2004 Page 1 of 1

1/31/2007 8:14:51AM

02/01/2001 11.08 FAX 314	vrtu	CELSIS LAB			Ø 028
	Interval	: 24 Month	Due: 2/12/2007	Sampl	eID#: R81282
Sample: Digitek (Digoxin)	Lot#:	5All3 (Mfg Ami	dc/Bertek Vendor#4277A	-	ANL #:
125 mcg (0.125 mg) Table		UVI Package		-,	
Date: Janland	SubDepartment:	HPIC		, the second sec	1498 Page: 4 of 7
1/29/07					Extra:
			Chromeleog	Pages:	
				*	
Analyte: Digoxi	~ (Noitak)	l de la la	•		g-independent control of the control
	~	TADACTS		_	ID# Reference
Method: USP		4-26-00-00-00-00-00-00-00-00-00-00-00-00-00	A STATE OF THE STA		
System Identification:		According to the second			and the second of the second o
Column:	and the state of t	,			
Mobile Phase: (37:13	H20: A(N)	2220	1 Millio Had	_	
(Building B) +	7805	ACNI (=:	to do the	_	
10x \$104511, exp	01102). HI	tered at	id degassed.	-	Minimizer and a second
Wavelength/Inj. Volume/Flow Standard Data <u>Billyed Akconol</u>	500-mi Eul			- Annoual Control	Elzek - V
Std Prep: Std was a (Bal 240) (See p. 14. 110mg - 0. 060mg = 1	Aried at 105°C 1050mg > 100	x 1 hour. Xin 10+0018916)	H Adjusted to : N	A	
. Purity Factor = 0.961 m	sing for RS	_			
Alston Suitzbillity Ro	SO :		n pH Meter# N	<u>R</u> or pH	IT# NA (pH tester)
1821 210) 4.041mg - 0.000 0x1210) 4.025mg - 0.011	Machineria	T KSS p	H Buffer Check(s)		
4.041mg=0.008mg= 4	1033 mg (USP Digo	ikin RS)	> 100.0ml (di	•	alcohol
ied std in Vacuum Ove	.009mg(Digoxia		× 1 hr (TM-77)		
3 Reprepped System S not pressing system	oitability Yrec	bechise	ither ortion it	Digoci	n RS was
Dispelling AEB 1/29/07 @	redrial and am	olador	· · · · · · · · · · · · · · · · · · ·		
Signature/date:	The state of the s	Reviewed by/d	ate:	ar - San Park (Marine) and Associated Associ	III Aliquid que expegação en
Form: SCH007.10 Effective: 10-17-2003	interese - Anticophysiografic - Spiritina and American and American - Group - GT SS Statistic Spiriting (SASS)		and benegation to the comment of any indicate and a second control of the comment of the comment of the comment	- 3° 934 Million of the state o	

01/26/2007 14:25:50

72007 17:05 FAX 314 487 8776 CELSIS LABS	-
Page:of	
Deviation and Discrepancy Report	
Date of Event: 1-8-07 Number: (07-007	
Discrepancy Deviation Planned Unplanned	
Description/Impact of Event The vacuum oven Currently in use pulls of such in a	7
Inescription/Impact of Event The vacuum over Currently in use pulls sometimes. Inches the which corresponds to Auches the	
The full vacuum was pulled when samples and standards	
for drying for an interior period until o new	
vocuum pump is purchased.	
Root cause: Varioum pump to Calibrated and a full vacuum is had after USP requirement was not met	
Jacum is used the USP requirement was not met	
due to the capability of the Vacuum	
50	
NH 17	
N <sup>H</sup> 1-11-07	
。 光光 光光 光光 光光 光光 光光 光光 光光 光光 医乳腺 医乳腺 医乳腺 医甲状腺 医甲状腺 医甲状腺 医甲状腺 医甲状腺 医甲状腺 医甲状腺 医甲状	
Corrective Action/Preventative Action: (1 Mw) nums will be	
Purchased, Calibrated of placed into service.	
N 11-01	
See attached	
Originator Signature/Date AM Millians 1-11-67	
Management Signature Date: Denies Man Sessee 21/11/2007	
QA Signature/Date: R. Jewell 1/12/07	
Form: #CAD028.1 Effective: 12/22/06 Page: 1 of !	

JAN. 29. 2007 11:56AM

MYLAN GSO QA

NO. 5006 P. 4



101 E. Main Street, Little Falls, NJ 07424 • Ph: (973) 8901440 • Fax: (973) 890-7980.

Digoxin Tablets, 0.25 mg

BATCH # 61097A

CERTIFICATE OF ANALYSIS GENERATED FOR CUSTOMER PURPOSES ONLY

All testing has been performed in accordance with GMP and GLP and all results have been found to comply with the registered specifications.

Part of Bulk Batch # 61097A is bottled as Control # 61097A1 (PACK SIZE 100)

Manufactured Date: 12/12/06

Approved By: Sala'
Regulatory Affairs

Date:

JAN. 29. 2007 IT:56AM

MYLAN GSO QA

NO. 5006 P.

Actavis Totowa LLC

### CERTIFICATE OF ANALYSIS

Product Name: Digoxin Tablets, 0.25 mg

Date of Analysis: 01/06/07 Control No: 61097A Exp. Date: December 2008

TEST	RESULT	
		Liber
DESCRIPTION: Color:	White	White
Profile:	Round bisected tablets	Round bisected tablets
Other: Debossed	"B 146" on bisected side	1
FRIABILITY:	0.1%	NMT 1.0%
IDENTIFICATION: (A)	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.
ASSAY:	The Rf value of test solution corresponds to standard solution.	The Rf value of test solution corresponds to standard solution.
Digoxin, 0.25 mg UNIFORMITY OF DOSAGE UNITS: (Content Uniformity) Digoxin, 0.25 mg	1) 98.6% 6) 100.5% 2) 101.8% 7) 101.2% 3) 102.7% 8) 102.9% 4) 100.7% 9) 100.0% 5) 101.2% 10) 100.6%	90.0% - 105.0% 85.0% - 115.0% RSD: NMT.6.0%
DISSOLUTION: Media: 500mL; 0.1N HCl Apparatus: I, RPM: 120 Temp: 37.0°C ± 0.5°C Time: 60 minutes	Average: 101.0% SD: 1.27%  1) 98.5% 4) 100.0%  2) 101.8% 5) 97.3%  3) 100.0% 6) 100.5%  Average: 99.7%	NLT 80 % (Q) of the labeled amount of Digoxin is dissolved in 60 minutes.
Related Substances: Digoxigenin Digoxigenin	0.276%	NMT 2.0%
bisdigitoxoside	Not detected	NMT 2.0%
Gitoxin	Not detected	MMT 3.0%

Director of Quality Control

02/02/2007 11:10 FAX 314 487 6776

CELSIS LABS

Ø001/050

## Celsis | Analytical Services

### Report of Analysis

Company:

Attn. Name: Thomas Spaine

UDL Laboratories, Inc.

Address: 1718 Northrock Court

City, State, Zip: Rockford, IL 61103

Sample ID#: 783543

Report Date: 02/02/2007

Received:

01/30/2007

Department: Chemistry Page: 1 of 7

Sample: Digitek 250 mcg

Lot #: 61097A1 (Skid #4 Top) exp 12/08

Test: Digoxin Assay

Method: Current USP and Supplements Claim: 250 mcg/tab (0.250 mg/tab)

Limit: 90.0 - 110.0%

Result: Date Assayed: 1/30/2007

256 mcg/tablet (102.4%) - Conforms

Test: Dissolution

Method:Current USP and Supplements Claim: 250 mcg/tablet 0.250 mg/tablet

Limit: NLT 85% in 60 min for the avg of tablets tested

Result: Date Assayed: 1/30/2007

Component: Digitek

Stag	9 1
Sample #	% Dissolution
1	97
2	94
3	95
4	100
5	99
, A	103
Average for 6	98

Conforms

Unless afternate arrangements have been made, sample will be retained for 30 days and raw data for 7 years after report date

Celsis Laboratory Group 6200 S. Lindbergh Blvd. St Louis, MO 63123 USA T+1 314 487 6776 F+1 314 487 8991 Colsis Analytical Services represents that this is a confidential report which may be used when requested by physician and health officials,

but is not to be used in any form of advantising without written permission Part of the Colsis International plc group of companies www.colsis.com

Desc; white plastic bottle  PO #: A29A3  Qty: I bottle 100 tablets  Log: 01/30/2007  Safety Name: No Safety Type  DEA #: N/A  Instructions: For all distinguistions report number of minutes, when possible. Send all data and reperts overnight  S1,575.00  Digoxin Assay  Critical USP and Supplements  Claim: 250 meg/tab (0.250 mg/tab)  Limit: 90.0-110.0%  SubDept: HPLC  Alert Limits: 93.3/- 100-179.©  Anc Bala: (Fe) No Anc Ref: 20002 21/m. 2000 21/2004 21/2007  Method Instructions: NA  43368 9 = 20 Not. 2.43 3409 = 20 tabs = 0.12/1689/tab x 1000 vay/g = 121/68 mg/tab x 1000 vay/g = 121/68 mg/ta		6776 CELSIS LABS	Ø 002/050
Desc: white plastic bottle  PO #: A29A3  Qty: 1 bottle 100 tablets  Log: 01/30/2007  Safety Name: No Safety Type  DEA #: N/A  Intervertions: For all distinguishors report number of minutes, when possible. Send all data and repara oversight  Intervertions: For all distinguishors report number of minutes, when possible. Send all data and repara oversight  Intervertions: For all distinguishors report number of minutes, when possible. Send all data and repara oversight  Intervertions: 50.000  O.00 %  SubDept: HPLC  Very Limit: 900-110.0%  SubDept: HPLC  Very Limit: 90.0-110.0%  SubDept: HPLC  Very Limit: 93.3! - 1132-121-120  Very Limit: 93.3! - 1132-121-120  Anc Data: (rep. No. Anc Reft: 1200-121-120-120)  Anc Data: (rep. No. Anc Reft: 1200-121-120-120-120-120-120-120-120-120	DL Laboratories, Inc	Due: 02/02/2007	Sample ID#: 783543
Obj. Thoule 100 tablets  DEA #: NA  DEA #: NA  Instructions: For all distinguations report number of minutes, when people. Send all data and reports overshiph  NA  Instructions: For all distinguations report number of minutes, when people. Send all data and reports overshiph  S1,575.00  Japan Assay  Area Tolor 110.0%  Results:  25 la may tab  (102. 4 //)  Limit: 90.0-110.0%  SubDept: HPLC  Mert Limits: 93.3 // - HELD DDD  Are Ref. 20072-21 from the 18054H Assay Date: 1/2017  deep tol N/A  Are Data: (res) No Are Ref. 20072-21 from the 18054H Assay Date: 1/2017  deep tol N/A  Assay Date: 1/2017  Assay Date: 1/2017  Assay Date: 1/2017  Assay Result: 0.2505 may tab x (1000 mg/mg) = 255.5 may tab x (1000 mg/mg) = 101.4 mg/mg/mg/mg/mg/mg/mg/mg/mg/mg/mg/mg/mg/m	Sample: Digitek 250 meg		
Instructions: For all distinct particles report number of minutes, when possible. Send all data and reports overnight  51,575.00  Digoria Assay  Claim: 250 meg/tab (0.250 mg/tab)  Limit: 90.0-110.0%  SubDept: HPLC  Alert Limits: 93.3/ 100.75 D  Anc Bala: (Pe) No Anc Ref: 200.02 21/m. m. 21825H Assay Date: 1/20/07  Method Instructions: LAA  43369 9 = 20 vvt. 2.43 3e0g = 20 +205 = 0.12/128 g/+200 x 1000 vvg/g = 121.128 mg/h  Assay Date: 1/20/07  Method Instructions: LAA  12320 9 = 20 vvt. 2.43 3e0g = 20 +205 = 0.12/128 g/+200 x 1000 vvg/g = 121.128 mg/h  Assay Date: 1/20/07  Method Instructions: LAA  12369 9 = 20 vvt. 2.43 3e0g = 20 +205 = 0.12/128 g/+200 x 1000 vvg/g = 121.128 mg/h  Assay Date: 1/20/07  Method Instructions: LAA  12369 9 = 20 vvt. 2.43 3e0g = 20 +205 = 0.12/128 g/+200 x 1000 vvg/g = 121.128 mg/h  Assay Date: 1/20/07  Method Instructions: LAA  12369 9 = 20 vvt. 2.43 3e0g = 20 +205 = 0.12/128 g/+200 x 1000 vvg/g = 121.128 mg/h  Assay Date: 1/20/07  Method Instructions: LAA  12369 9 = 20 vvt. 2.43 3e0g = 20 +205 = 0.12/128 g/+200 x 1000 vvg/g = 121.128 mg/h  Assay Date: 1/20/07  Method Instructions: LAA  12300 9 = 20 vvt. 2.43 3e0g = 20 +205 = 0.12/128 g/+200 x 1000 vvg/g = 121.128 mg/h  Assay Date: 1/20/07  Method Instructions: LAA  12369 9 = 20 vvt. 2.43 3e0g = 20 +205 = 0.12/128 g/+200 x 1000 vvg/g = 121.128 mg/h  Assay Date: 1/20/07	PO #: A29A3	Qty: 1 bottle 100 tablets	Log: 01/30/2007
Results:  256 May tab  Claim: 250 mcg/tab (0.250 mg/tab)  Limit: 900-110.0%  SubDept: HPLC  Mer Limits: 93.3/ - 1020-120  Mer Limits: 90.0 Anc Reft: 2000-120  Mer Limit: 90.0 Anc Reft: 2000  Mer Limit: 90.0 Anc	Safety Name: No Safety Type DEA#: N/A	Corrections:	2 iscours
Claim: 250 mcg/tab (0.250 mg/tab)  Limit: 90.0-110.0%  SubDept: HPLC  Meri Limits: 93.3! - HSQ-120 D  Meritable Instructions: NA  Anc Data: (re) No Aac Ref: genger 21 mm me 1855H Assay Date: (120/b1)  Rethod Instructions: NA  43568 9 = 20 mt . 2.43 3 e0g = 20 +20s = 0.12 1/e8 a/+20 × 1000 ms/g = 121.68 mg/s  Meritable Instructions: Na  May cavara claim: 0.250 mg/tab 121.68 mg/s  May cavara claim: 0.250 mg/tab 2 mg/s  May cavara claim: 0.250 mg/tab 2 mg/s  May cavara claim: 0.00 mg/	Instructions: For all disintegrations report muni	ber of minutes, when pressible. Send all data and reports overnight	\$1,575.00
Claim: 250 meg/tab (0.250 mg/tab)  Limit: 90.0-110.0%  SubDept: HPLC  Meri Limits: 93.3/2 - 1000-77/2 (1000-77/2)	Digoxin Assay	Results:	
Limit: 900-110.0%  SubDept: HPLC  Mert Limits: 93.3! - H00-171.0  Anc Data: (Pa) No Anc Ref: 200022 21/100 mod 180044 Assay Date: (1/20/07)  Method Instructions: NAR  43568 9 = 20 wt. 2.43 3e0g = 20 +2b5 = 0.12 168 9/+2b × 1000 voy/g = 121.68 mg/4  May explain claim: 0.750 mg/+2b 121.48 mg/+2b × 1 mg = 486, 72 mg spl needed  20 v 2.1-07 Need: 1 mg 121.48 mg/+2b × 1 mg = 486, 72 mg spl needed  20 v 2.1-07 Need: 1 mg 0.250 mg/+2b × 1 mg = 486, 72 mg spl needed  20 v 2.1-07 Need: 1 mg 0.250 mg/+2b × 1 mg = 486, 72 mg spl needed  486.9 mg sample transferred to 2 glass-stoppered, 50-ml conical  486.9 mg sample transferred to 2 glass-stoppered, 50-ml conical  (SON-2) × 30 min, and cocked. Filtered 2 portion through  2 0.8-um membrane filter, discarding the first 10 ml glittrade.  Assay Result: 0.2555 mg/tab × (1000 mg/mg) = 255.5 mg/tab			
SubDept: HPIC  Meri Limits: 933/- 100079000000000000000000000000000000000	Limit: 90.0 - 110.0%	(102.47.)	
Anc Data: (Yes) No Anc Ref. 1982 21 mm and 183544 Assay Date: 1/30/07  Method Instructions: NAA  43568 3 = 20 mt. 2.43 360g = 20 +205 = 0.12/168 g/+20 x 1000 mg/g = 121.168 mg/g  And 124 21.07 Claim: 0.250 mg/+20 121.168 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Claim: 0.250 mg/+20 121.168 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 0.250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 0.250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 0.250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 0.250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 124 250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 124 250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 124 250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 124 250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 124 250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 124 250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.07 Need: 1 mg 124 250 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 mg/+20 x 1 mg = 486, 72 mg spl necessed  And 124 21.08 m	SubDept: HPLC		
Assay Result: 0.2555 maytab x 1000 mg/mg) = 255.5 mg/tab  (1360 g) = 20 mt. 2.43 3e0g = 20 tabs = 0.12168 g/tab x 1000 mg/g = 121.68 mg/mg/mg/mg/mg/mg/mg/mg/mg/mg/mg/mg/mg/m	Alen Limits: 93.3/ 100.77	<b></b>	N/A
ASSAY Result: 0.2555 ma/tab x 1000 mg/mg) = 255.5 mg/tab  (20 Claim: 0.2550 mg/tab 21. UB mg/mg/tab)  ASSAY Result: 0.2555 mg/tab x 1000 mg/mg) = 255.5 mg/tab  (20 Claim: 0.2555 mg/tab x 100% = 255.5 mg/tab	Anc Data: Yes No Anc Ref: pos	1832 21 mg and 183544 Assay Date: 1 30107	A STATE OF THE STA
All evering Claim: 0.250 mg/tab 121.48 mg/tab x 1 mg = 486.72 mg spl nearled  3.250 mg/tab x 1 mg 8.250 mg/tab x 1 mg = 486.72 mg spl nearled  3.250 mg/tab x 1 mg 9.250 mg/tab x 1 mg = 486.72 mg spl nearled  3.250 mg/tab x 1 mg 50 med conical  3.219 Spl Rep:  486.9 mg sample transferred to 2 glass-stoppered, 50-ml conical  (50N-2) x 30 min; and cooled. Filtered 2 portion through  2 0.8-um membrane filter, discarding the first 10 ml g  filtrade.  Assay Result: 0.2555 mg/tab x (1000 mg/mg) = 255.5 mg/tab  (100 claim: 256 mg/tab x 100% = 102.4%	Method Instructions: HA		,
1. 8 claim: 256 mg/tab x (1000mg/mg) = 255.5 mg/tab  1. 8 claim: 256 mg/tab x 100% = 102.4%	CSN N S-1-01 NEEGE , I wa	0.250 mg/tab	24.
	32119) Spl Rep: 486.9 mg sample tran 120107 black. Added (SON-2) x 2 0.8-un		
	32119) Spl Rep: 486.9 mg sample tran 120107 black. Added (SON-2) x 2 0.8-un biltrade.	nsferred to a glass-stuppered, of 25.0-ml (diluted alcohol) will 30 min, and cooled. Filtered in membrane filter, discarding	50-ml conical ith swirling, sonicad a portion through the first 10 ml &
	32119) Spl Rep: 486.9 mg sample tran 120107 blask. Added (SON-2) x 2 0.8-un biltrade. Assay Result: 0.25	referred to 2 glass-stoppered,  25.0-ml (diluted alcohol) wi  30 min, and cooled. Filtered in membrane filter, discarding  555 mg/tab x (1000.mg/mg) = 20	50-ml conical ith swirling, sonicad a portion through the first 10 ml of
	32119) Spl Rep: 486.9 mg sample tran 12007 blask. Added (SON-2) x 2 0.8-un biltrade.  Assay Result: 0.25 1. of claim: 256 u 250 u	respected to 2 glass-stuppered, 25.0-ml (diluted alcohol) with 30 min, and cooled. Filtered in membrane filter, discarding 555 mg/tab x (1000.49/mg) = 24/42b x 100% = 102.4%.	50-ml conical ith swirling, sonical a portion through the first 10 ml of
	13219) Spl Rep: 486.9 mg sample tran 13007 blask. Added (SON-2) x 2 0.8-un biltrade.  Assay Result: 0.25 1. of claim: 256 u 250 u	respected to 2 glass-stuppered, 25.0-ml (diluted alcohol) with 30 min, and cooled. Filtered in membrane filter, discarding 555 mg/tab x (1000.49/mg) = 24/42b x 100% = 102.4%.	50-ml conical ith swirling, sonical a portion through the first 10 ml of
	186.9 mg sample transport	respected to 2 glass-stuppered, 25.0-ml (diluted alcohol) with 30 min, and cooled. Filtered in membrane filter, discarding 555 mg/tab x (1000.49/mg) = 24/42b x 100% = 102.4%.	50-ml conical ith swirling, sonical a portion through the first 10 ml of

02/02/2001 II. 10 PAA 314 481 0//	6 CELSIS LAN	B3	
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		•	
CAR	Due: 2/2/2007		Sample ID#: 783543
SubDepartment: HPLC		ANL#:	Page: 2 of 5
		1 498	Extra: NA
	- Committee of the Comm	Chromel	
		(VIII OME)	eon Pages: No
•			7
6			
Analyte:	,		ID# Reference
Method:			R81282-24mo
			783544
System Identification:			- 100511
Column:			
		/	-
Mobile Phase:			NA /
	7		
			/2/1/07
		And the second s	
Wavelength/Inj. Volume/Flow Rate:			
Slandard Data			
	/		
NA			•
lor'/	. ·•	ald Auditoria and Accord	
		oH Adjusted to :	The second secon
/ / A	toB v	vith(pH adjust	NA
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	2/1/01 .0	on pH Meter #µA	or pHT# NA
		H Buffer Check(s)	(pH tester)
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	and the second s		
Signature/date: Bischett 2/1/0	Reviewed by/o	tate: // \/ \	
orm: SCH007.10		Jale: Christagli	-3/2/07
ffective: 10-17-2003		O	
age 2 of 2	•		

02/02/2007 11:10 FAX 314 487 6776	CELSIS LABS	M-CHARLES AND	@ 004/050
	Due: 2/2/2007	Sai	mple <b>ID#:</b> 783544
SubDepartment: HPLC		ANL#:	Page: 2 of 5
		498	Extra: NA
Sequence #5 0	20107-498-2 20107-498-3	(3) Chromeleon Pa	ges: 1-12A
Analyte: Digoxin (	Digitek) tab	Net5	
Method: USP 29			1D# Reference (28)282-
System Identification: LC-2	. •		24m0
Column: H-39 Epic e18	Su 120Å 25cm	n × 4.2mm	783543
S/N. 16104-14-78-51399 Mobile Phase: 127:13 11-0: ACT	guard column : Epic	- CY8 & SIN: 23704 - CY8 & SIN 14-91-5	+-
Mobile Phase: 137:13 420: AC	W 1480 ML MI	111-0 H20	^
(BId-B) + 520-mL A	iON (Fisher Option	na lot outs!!	NA /
exp 01/08). Filtered 2	nd degassed.	,	AEB 24/107
40			
Wavelength/Inj. Volume/Flow Rate:	218-nm/50ul	13.0m1/min	- <del> </del>
Standard Data			/
Sid Prep: USP Digoxin RS 1	lot ODBOALE)		
(1981 24) 4.0145 0.01200 = 4.00400 Std Concentration = 4.00400g/ Purity Factor: 0.461 mg/mg for	19 > 100.0ml (di 100.0ml= 0.04004m RS	iuted ot) glmL idjusted to:N	ANCILLARY
System Suitsbillity Rep: (USP Dig	orin RS? Diapopoporin)		i A
4.098=0.001 mg = 4.097 mg	1.01.0)	(pH adjusting sol	
USP Digorn RS 4.009mg 4.009mg	On ph b (diwhed OH) ph B	H Meter# NA or	pHT# NA (pH tester)
Note: see pulot of R8128	2-24mo for std	drying and dilux	ed alcohol prep
(Don't needed ABB 21/107 (2) wardin	n Afazirim		
Signature/date; Bischell 24	2/07 Reviewed by/date:	Marin	
Form: SCH007.10 Effective: 10-17-2003 Page 2 of 2		Chraslandh z	2 [07]
· wayor da Sir pu			

2/02/200/ 11:11 FAX 314 487 6776

CELSIS LABS

Ø005/050

		Ch	romatography	Report		
. ~	uence Title:	Digoxin Assay			Total Samples:	11
	uencé Name:	020107-498-2b			Sample No.:	
1 -	tem ID:	LC-22			•	
1	-	02/01/07 14:28:51				
4	rted by:	Anna Bischoff				
-	ation:	ServerData	2007/1 JAN THRU	MARCH\488		
-	bration					•
No.	Peak Name		Cal.Mode	Cal.Type	#Points	Corr.Coeff. %
Peal	Analysis					
No.	Peak Name		Resolution (USP)	Tailing	Plates (USP)	K'
Syst	em Suitability		Marketon and the State of the S	·		
,			n.a.	n.a.	n.a.	n.a.
No.	Name					
			UV VIS 1	UV VIS 1	UV_VIS 1	UV VIS 1
7	Standard 1		n.a.	9.27425808	n.a.	n.a,
10	Standard 2	1 - 1	<u>L.                                    </u>	9,28040090	n.a.	n.a.
	j	%RSD	#DIV/0!	0.047	#DIV/0!	#DIV/0!
	/st Signature/Date:	Anna Bist Chemi	st		ANCII	LLARY
QC R	levlew/Date:	_ Chris Varah	2207			

added p IA to show system suitability
AB 2/1/07

6.70 SP2a Build 1871 Version Number 2.2

Page 1 of 12

02/02/2007 11:11 FAX 314 487 6776

CELSIS LABS

Ø006/050

		Ch	romatography	Report		
	uence Title:	Digoxin Assay	8	Manair	T-1-10	
	uence Name:	020107-498-2			Total Samples	
	tem ID:	LC-22			Sample No.:	: 11
Proc	essing Date/Time:	02/01/07 14:20:34				
Crea	nted by:	Anna Bischoff				
Loc	ation;	ServerData	Opposit tassesses			
Call	bration	The state of the s	2007/1 JAN THRU	MARCHI498		
No.	Peak Name		Cal.Mode	CIF		ş - ***********************************
				Cal.Type	#Points	Соп.Соеп.
1	Digozygenin		Total			%
2	Digoxin		Total	Lin	5	99.997
Peak	Analysis		1 Julia	L Lin	5	99.990
No.	Peak Name		Resolution			
			/	Tailing	Plates	ĸ
1	Digoxygenin		(USP)		(USP)	
2	Digoxin		13,49	2.46	1187	n₋a,
Syste	em Suitability		n.a.	1.96	1607	n.a.
				•		A CONTRACTOR OF THE PROPERTY O
			Digoxygenin	. Digazin	n.a.	na.
No.	Name					
2	Contract to the terms of the te		UV VIS 1	_UV VIS 1	UV VIS 1	_UV VIS 1
3	System Suitability 1		19.61372095	9.06532399	n.a.	
-	System Suitability 2		19.56334623	9.04740426		<u>n.a.</u>
	System Sultability 3 System Suitability 4		19,58746710	8:97129354	n.a.	n.a. n.a.
	System Suitability 5	***************************************	19,70433584	8.92523679	n.a.	n.a.
		6RSD	19,54114496	8,99209405		
		SUST	0.323	0,633	#DIV/0!	#DIV/01
nalys	t Signature/Date:	B'sctoff Anna Bish	5 2/1/07		AN	CILLARY

Anna Bischoff Chemist

6,70 SP2a Build 1671 Version Number 2.2

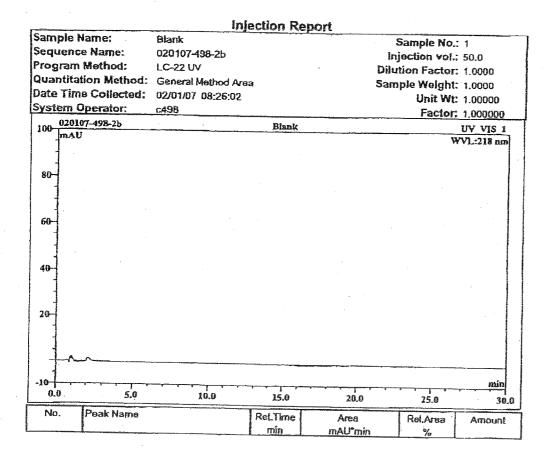
QC Review/Date:

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Added page

. of Loof 11.11 15M 514 407 0770 CELSIS LABS 4007/050



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Chris Vende 2/2/07

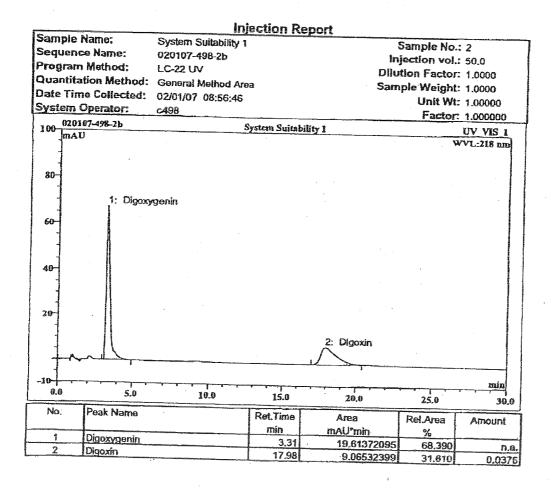
6.70 SPŻa Build 1871 Version Number 2.2

Page 2 of 12

02/02/2007 11:11 FAX 314 487 6776

CELSIS LABS

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Chris Vengle 2/2/07

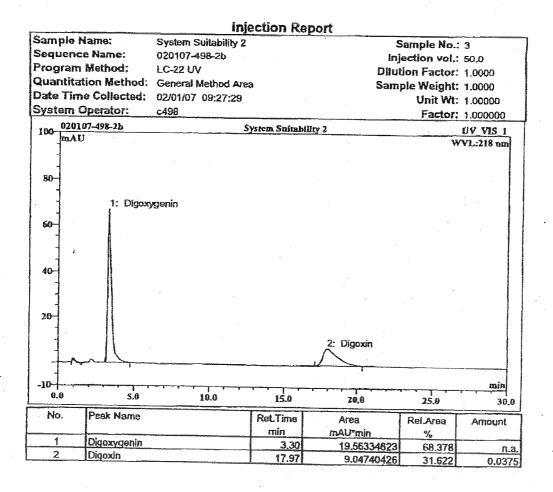
6.70 SP2a Build 1871 Version Number 2.2

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02/02/2007 11:11 FAX 314 487 6776

CELSIS LABS

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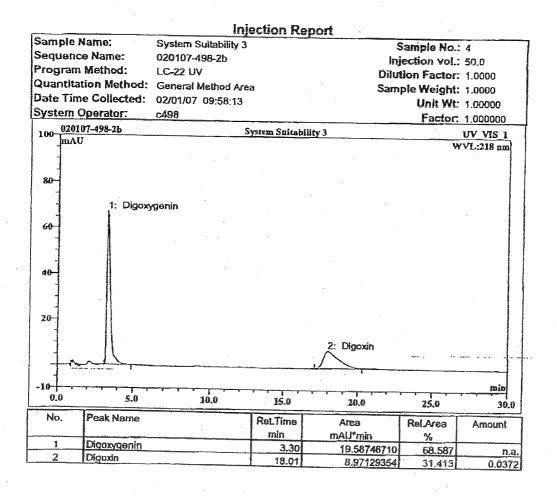
6.70 SP2a Build 1871 Version Number 2.2

Page 4 of 12

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CELSIS LABS

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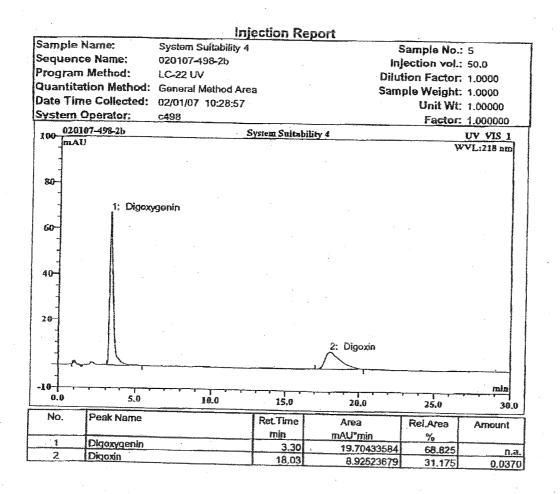
Chris Vangle 2/2/07

6.70 SP2a Build 1871 Version Number 2.2

Page 5 of 12

CELSIS LABS

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Chris Vangh 2/2/07

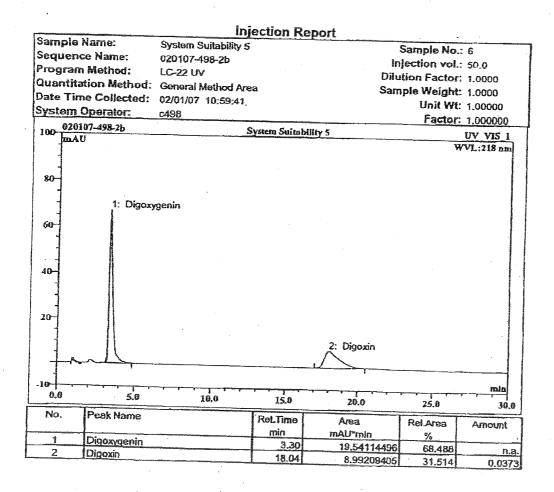
6.70 SP2a Build 1871 Version Number 2.2

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2/02/2007 11:12 FAX 314 487 6776

CELSIS LABS

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ANCILLARY

Chris Vauga 2/2/07

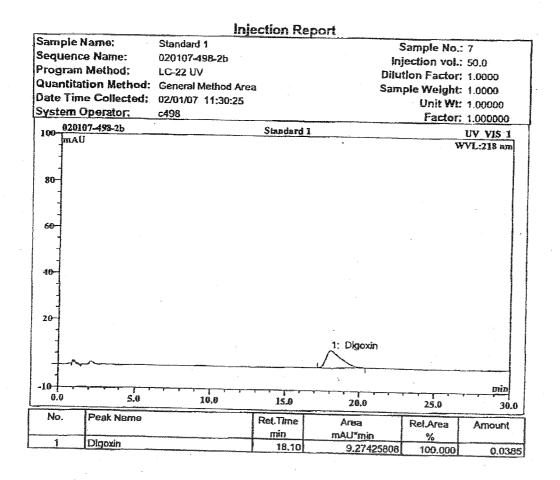
6,70 SP2a Build 1871 Version Number 2,2

Page 7 of 12

/UZ/ZUU1 11:12 FAX 314 487 6778

CELSIS LABS

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Chris Vaugu 2/2/07

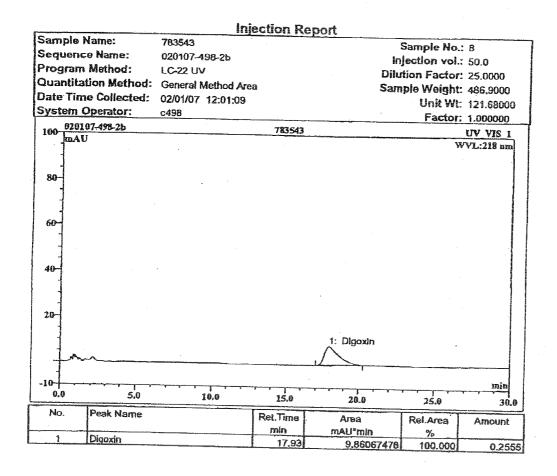
6.70 SP2a Build 1871 Version Number 2.2

Page 8 of 12

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CELSIS LABS

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Christand 2/2/07

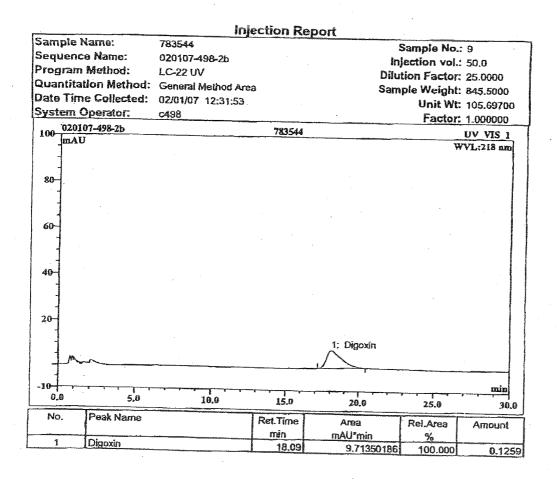
6.70 SP2a Build 1871 Version Number 2.2

Page 9 of 12

7027 2007 11.12 PRA 314 407 0770

ELSIS LABS

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Chris Vargher 2/2/07

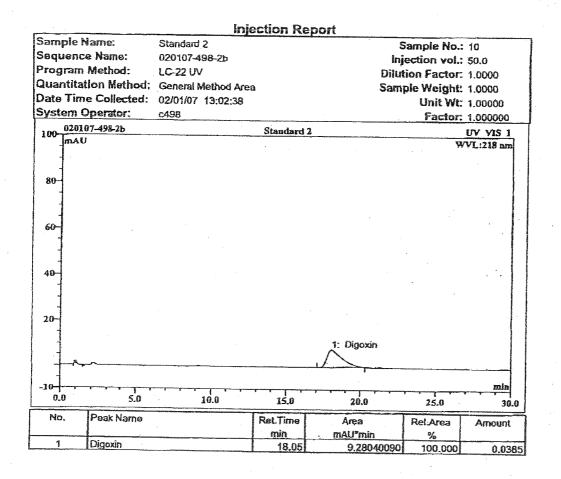
6.70 SP2a Build 1871 Varsion Number 2.2

Page 10 of 12

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CELSIS LABS

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ANCILLARY

Chris Vaugl 2/2/07

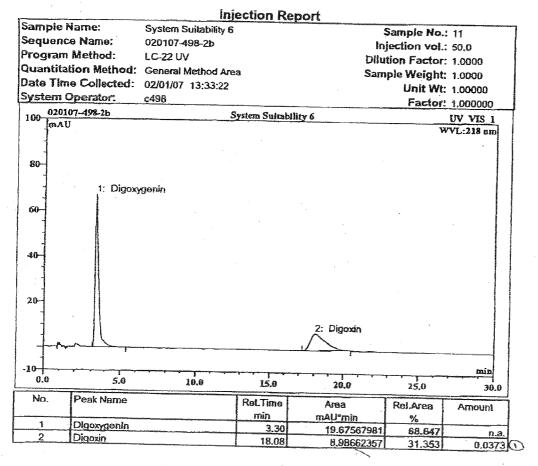
6.70 SP2a Bulld 1871 Version Number 2.2

Page 11 of 12

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CELSIS LABS

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Othis value calcid as a spl, but not used in any sample calculation. ABB 2/2/07

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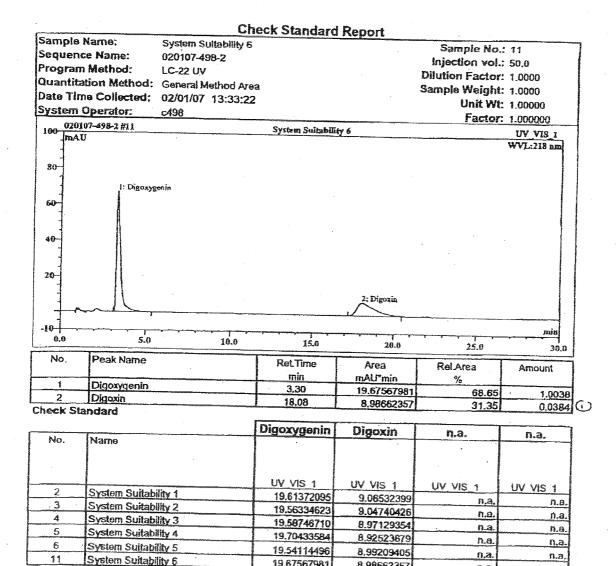
Christangen 2/2/07

added p 12A to show system set.

Page 12 of 12

24107

current date:2/1/2007 current time: 2:29 PM

6.70 SP2a Build 1871 Version Number 2.2 

Othis value used to calc. system sustability. Not used to calc. spl. zunt. ABB . 2/2/07

19,67567981

0.327

ANCILLARY

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#DIV/01

Page 10/1 2dded page ABB 2/1/07

8,98662357

0.570

current date:2/1/2007 current time: 2:35 PM

<u>n.a</u>

6.70 SP2a Build 1871 Version Number 2.2

LXRSD

P and Supplemen 250 mcg/tablet 0. N <del>TL 60% in 30 n</del> 50 min Dissolution	grations report number of	Qty: 1	61097A1 (Skid #4 To white plastic boule i bottle 100 tablets corrections: nm 1/38/D7 sible, Send all data and	NLT 85%	(Q) In 30°	Log: Comm	3 of 5 MA 01/30/2007
A29A3  rne: No Safety T  A #: N/A  ons; For all disinte  P and Supplemen  250 mcg/tablet 0.  NTL 60% in 30 m  Dissolution	grations report number of its 250 mg/tablet	Qty: 1	white plastic bottle bottle 100 tablets corrections:	NLT 85%	(Q) in 305	Log: Comm	MA 01/30/2007
rne: No Safety T A #: N/A ons: For all disinte P and Supplemen 250 mcg/tablet 0. NTL 60% in 30 m Dissolution	grations report number of its 250 mg/tablet	minutes, when pos	corrections:	A	(Q) in 305	Log: Co Omin	)1/30/2007 20 <sup>9</sup> 7.
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ons; For all disinte. P and Supplemen 250 mcg/tablet 0. NTL 60% in 30 a 50 min Dissolution	nts 250 mg/tablet	rainutes, when pos	nm 1/38/07 sible. Send all data and	A	JA.	traction acu	奔 .
P and Supplemen 250 mcg/tablet 0. N <del>TL 60% in 30 n</del> 50 min Dissolution	nts 250 mg/tablet	A CONTRACTOR OF THE PARTY OF TH	Stole, Send all data and	tebour overnight			100
250 mcg/tablet 0. NTL 60% in 30 n 60 min Dissolution	250 mg/tablet						\$3,810.00
NTL 60% in 30 n 50 min Dissolution	_						\$0.00 % 00.0
50 min Dissolution	<del>rin and</del> NLT 85% in					-	\$3,810.00
Dissolution		` .	See	Belo	\X7(		GCH
					AA		conforms .
ts:	)A					1	does not
(Yes) No	Anc Ref: 783	54Q	Assny Date	e: 1/2=/	The second secon		N/A
tructions:	νA			" (130/0")		***************************************	
Stage 1	Results				Manufacture of the second seco	······································	**************************************
nple No.	% Dissolution	on \	\				
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04.8	113			The same of the sa	chilo()		
	Stage 1 nple No. 1 2 3 4 5 6 age for 6	Stage 1 Results  Inple No. % Dissolution  1 97 2 94 3 95 4 100 5 99 6 103 age for 6 98	Stage 1 Results  Inple No. % Dissolution  1 97 2 94 3 95 4 100 5 6 103 Inge for 6 78  Addate: A 100  Addate: A 100  A 100	Stage 1 Results  Inple No. % Dissolution  1 97 2 94 3 95 4 100 5 99 6 103 Ige for 6 98  Make Indian Reviewed by/date: Ind	Stage 1 Results  Pople No. % Dissolution  1 97 2 94 3 95 4 1000 5 99 6 103 age for 6 98  Pople for 6 98  Pople No. % Dissolution  1 97 2 94 3 95 4 1000 5 99  Pople No. % Dissolution  1 97 2 94 3 95 4 1000 5 99  Pople No. % Dissolution  1 1 97 2 94 3 95 4 1000 5 99  Pople No. % Dissolution  1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Stage 1 Results  Table No. % Dissolution  1	Stage 1 Results  Inple No. % Dissolution  1

OLIOLILOUI II.IT IAA JIT	401 0110 CEF212 FWR2		<b>4J0207050</b>
C. I P	Due: 2/2/2007	Sampl	e ID#: 783543
SubDepartment: Dissolution		ANL#:	Page: 4 of 5
Control of the state of the sta		120 120	Extra: NA
Check	list Procedures for USP Apparatu	S (1) OR II (circle one)	
Apparatus ID#: 6	Volume: 500 mL Time:	60min Timer#: Tm -	.76
Medium: 0-1 N HCI			
58 ml HCl (Fisher,	Lot # 060506, 10-09, 12.i		
		Heated and De	gassed . OL 30-07
pH: (IF APPLICABLE): pH Test	ter ID:		wh
Buffer S	Set Value: Check Va	lue: Media Valu	i <del>o.</del>
Buffer it	fanulacturer, Lot# and Expiration Da	ite: NA man ilsolo	
<ol> <li>Inspect all paddles or ba and check the verticality</li> </ol>	skets, shafts, and vessels for cleant shaft. Pas	iness, deformations, burrs, or others	ner defects,
2. Check the adjustment of	each assembly so that each paddle	or basket is	
	4.5 cm (circle one) 1/6-3		
above the inner floor of t	he vessel. The tolerance is 2 mm. t	Each shaft is marked to	
to the correct height. All	are within tolerance Pas	S ⇔ I can be	returned
<ol><li>Measure temperature of</li></ol>	the water bath. The tolerance is 37°	± 0.5°C. Pass ⇒	
Temperature:	37.	rmometer #:	
<ol> <li>Select the gear drive or a Turn on the motor drive</li> </ol>	adjust the speed control to obtain the Measure the shaft resolutions per mathematic properties and the state of the machine to the fire speed to the state of the machine to the state of t	revolution speed specified in the	
Speed (rpm):	120.0		
	raightness. Install shafts, start mo out gauge against each shaft just al in tolerance.	tor, engage clutches, and mea pove the paddle of basket. The	sure the amount of tolerance is 1 mm
Wobble Gauge ID:	W6-9		
1. <u>10.1001</u> 2.0	0.004 3.15.004 4.1	9.007 5.0004	6 (2 : COS)
6. Measure the temperature Thermometer #:	of the medium in each dissolution ve		
1. 37.3 2. 3	3.37.0 4.	37. 2 5. 3)-1	6. 37-/
Signature/Date:   / L   / U	L 1/30/07 Reviewe	ed By/Date: ChieVand	
Form: SCH004.8 Effective: 08-09-2002 Page 2 of 3	<del></del>	X )	2/1/07 when to write y date CZU 2/1/07
			1 · · ·

01/30/2007 10:00:51

UZ/UZ/ZUU7 11:14 FAA 314 487 8776 CELSIS LABS Ø021/050 Due: 2/2/2007 Sample ID#: 783543 SubDepartment: Dissolution ANL #: Page: 5 of 5 420 Extra: NA

Additional Analytical Worksheet

See R8 1989 24 mo for std stock pray into we reproped. see 7635-12 for who std a solution preparations.

withdraws AP 20me samples and feltered with a 0.45 w Nylon disc discording 15t 10me

to 1. One Blank, 1.0 me each standard, 1. One each sample solution.

in deplication.

1/20/07

- is added 1. One assorber and solution and swithed
- 2) added 5.0 ml Hel (Cishwest cooses 10/19) and swithed
- 3) added 1. One Hydrodon provide muthand soln and swithed and

-783542 See pg 5A for std also readings See 783542 pg3 of5 for Ad calibration wive

	16t 5et	3rd 	ave
~1	730	709	730
ius	716	700	708
. v3	715	720	718
V4	760	750	755
is	754	735	745
ν6	761	790	.776.
std 100%	734	728	126

Signature/Date: Form: SCH004.8 Effective: 08-09-2002 Page 3 of 3	lefox	· 1/3/107	Reviewed By/Date:	his Vargh = 2	11/07

01/30/2007 10:00:51

UDL Laboratories, Inc. Due: 02/02/2007 Sample ID#: 783542 Sample: Digitex Lot #: 61100A1 (Skid #7 Top) exp 12/08 Page: 3 of 5 250 mcg Desc: white plastic bottle Extra: N/A PO #: A29A3 Qty: 1 boule 100 tablets Log: 01/30/2007 Corrections: Safety Name: No Safety Type correction required. 9 NLT 85% 60 mg. DEA #: N/A Instructions: For all disintegrations report number of minutes, when possible. Send all data and reports overnight \$3,810.00 Dissolution Results: \$0.00 Current USP and Supplements 0.00 % \$3,810.00 Claim: 250 mcg/tablet 0.250 mg/tablet 480 Limit WLT 60% in 30 min and NLT 85% in 60 min conforms SubDept: Dissolution does not Alert Limits: N/A Anc Ref: 783542 Anc Data: (Yes) Assay Date: 01-30-07 idethod Instructions: Osec Clical E-mail for Limit - 01-31-07/m7 Ong.info. 01-31-07-my Stage 1 Results USP-29 ONLINE (DIGOXIN) Sample No. % Dissolution 1 94 % Dissolution (x) 2 Response(Y) 89 19.362228 3 97 1.0 mL 124 4 38.724456 97 2.0 mL 271 5 99 58.086684 412 3.0 mL 6 77.448912 94 4-0 mL 581 Average for 6 96.81114 732 50 mL ANCILLARY FACTOR -5.037 ms x 10.0 mL x 500mL x 1.0mL x 0.961mg x 100
100.0 mL x 50.0 mL x 0.250 mg x 100.0 mL x 1 mg

FACTOR - 19362228 CORR. COEF = 0.999574279 Sample % Dissolution from STD Curve.

Signature/date: Hucuff /o1-31-07 Reviewed by/date: Form: SCH004.8

Effective: 08-09-2002 Page 1 of 3

01/30/2007 11:08:55

Ø 0227050

UZ/UZ/ZUUY 11:14 FAX 314 487 6776

CELSIS LABS

Ø 023/050

Due: 2/2/2007 Sample ID#: 783542 SubDepartment: Dissolution ANL#: Page: 5 of 5 480 01-30-07 Extra: 5A - 5Bprep was OFF. Reprep all solutions. ANCILLARY Additional Analytical Worksheet mw 2/1/07 STANDARD = DIGOXIN (USP-STD, Lot # 00B096, 0.961 mg/ger mg) 281282 24 mo. STD Drying and Stock Std. WORKING STD = 10.0 ml STOCK STD - 50.0 ml 4 IN 5 ALCOHOL Glosswore rinsed with HCI (Fisher, Let # 060506, 10-09, 12.1 N), DI Water, and Alcohol (Aaper, Lot + Ohl1668, 3-10) and corefully dried. 4 IN 5 ALCOHOL = 160 ml Ethyl Alcohol (Adrer, Lot # 041166B, 370) \_\_ 200.0 ml H20 ASCERBIC ACID - METHANOL SOLUTION -Ascorbic Acid ( Sigma, 063 K1082, 8-10) \_\_ 100.0 ml Bol = 19 200.0 mg Methanol (Sigma) 20561HE, 1-08) MEthano 1 HYDROGEN PEROXIDE - METHANOL SOLUTION : WORKING = 2.0 ml Hydrogen Peroxide Stock 100.0 ml Methonol \* 2MOITUJOS GRADARTS 1.0 ml (20%), 2.0 ml (40%), 3.0 ml (60%), 4.0 ml (80%), 50 ml (100%) - 100.0 ml MEDIUM. + TABLET - 500 ml MEDIUM Filtered with 0.45 micros Nylon filter. Signature/Date: 464444 01-31-07 Reviewed By/Date: Form: SCH004.8 Effective: 08-09-2002 Page 3 of 3

01/30/2007 11:08:55

02/02/2007 11:15 FAX 314 487 6776

CELSIS LABS

@024/050

ML Laboratories, Inc. Due: 2/2/2007 Sample ID#: 783542 Sub Dept: Dissolution ANL #: docson + need. Page: 480 01-30-07. 01-31-07

Additional Analytical Worksheet

[Re-prep all solutions at 01-31-07 (see page 5B), used some Stock Disc. samples, and followed seme procedure below and Reed in Frie)

1.0 ml Medium as Blank, 1.0 ml each Standard

Solutions and 1.0 mL each Sample Solutions.

(wd PPT-7) Added 1.0 mL Ascorbic Acid-Methanol Solution and swilled. Added

5.0 mL HCI (Fisher, Lot # 060506, 10-09) and swilled. Hydrogen Peroxide - Methanol Working Solution Added 1.0 mL swilled than and capped allowed to sit 2 hours, Tm-54 and

FMR-I GAIN = 1000 SPAN = MAX

fluorescence = 485 nm Excitation wavelength = 372 nm. Excitation Filter = NB360 Emission Filter = SC415

3 crock	d with	Blenk	Duplication	Average
STD	20 %	125	123	124
510	40%	274	268	271
272	60%	409	414	412
a72	80%	574	585	581
STO	100%	739	724	732

		Duplication	_Average
Sample VI	696	713	705
Sempic Vz	734	736	735
Sample V3	733	729	731
Sample V4	737	726	732
Somple V5	742	748	745
Somple V6	709	707	708
\$ 00 dts	724	728	726

ANCILLARY = 783542 783543 783544

ANCILLARY

Signature/Date: 4/44 01-31-07 Reviewed By/Date: Form#: SCHC001.4

Effective: 04-02-2004 Page 1 of 1

1/30/2007 11:11:17AM

UDL Laboratories, Inc Due: 2/2/2007 Sample ID#: 783542 Sub Depr: Dissolution ANL #: Page: 5 B 480 01-31-07 N/A Additional Analytical Worksheet DIGOXIN (USP-STD, Lot = DOBOGE, G. 961 mg/pcr mg) [[(C)() SEE R81282 24 mo. for STD drying and Stock STD.

(Page 4 of 7) Bal = 26 5.065 mg - 0.028 mg = 5.037 mg STD = 100.0 mL 4 IN 5 ALCOHOL 10.0 ml STOCK STD \_ 50.0 ml 4 IN 5 ALCOHOL 4 IN 5 ALCOHOL = 160 mL Ethyl Alcohol (Ager, Lot # 04166B, 3-10) -, 200 0 ml H20 ASCERBIC ACID - METHANOL SOLUTION = 200.00 mg Ascorbic Acid (Sigma, 063K1082, 8-10) -100.0 ml Mothanol (Sigma, 00561HE, 1-08) HYDROGEN PERCXIDE - METHANOL SOLUTION = STOCK = 2.0 mL Hydrogen Peroxide (Sigmo, 095K3774,5-07) -, 100.0 ml Methanol (Sigma, 00561HE, 1-08) WORKING: 2.0 ml H202-Methanol Stock \_ 100.0 ml Methanol STANDARD SOLUTIONS -1.0 ml (20%), 2.0 ml (40%), 3.0 ml (60%), 4.0 ml (80%), 5.0 ml (100.0 %) 100.0 ml MEDIUM. See page 5A to fallow FMRI reading and prep. ANCILLARY

M/A 01-31-07 MY

Signature/Date: Whow the 101-31-07 Reviewed By/Date: Chis/augh 1/31/07

Form#: SCHC001.4 Effective: 04-02-2004 Page I of I

16

1/31/2007 8:14:51AM

02. 02. 2001 11.13 PAA 315	1 467 0716 CEL	SIS LABS	idinalini ini immining <u>uring (AMIDIN) ini dira conquest conquest conquest ini ini ini ini ini ini ini ini ini in</u>	t to a second control of the second control	Ø]026/050
-	Interval: 24 h	<b>Month</b>	Due: 2/12/2007	Sample	ID#: R81282 -
Sample: Digitck (Digoxin)	Lot #: 5A113	3 (Mfg: Amide/I	Bertek Vendor # 4277A		ANL#:
125 mcg (0.125 mg) Tab	lets, USP Desc: UVI F			,	
Date: 1/29/07	SubDepartment: HPLC		**************************************		Page: 4 of 7
112701					Extra:
			Chromeleon	Pages;	
	•				
					•
Analyte: Digox		<u>udets</u>	_@(C(M))	РYГ	ID# Reference
Method: USP	OL 29	**		1 11	
System Identification:				-	
				-	
Column:					
		· · · · · · · · · · · · · · · · · · ·	17.74500	-	
Mobile Phase: (37:13	H20: ACN) 22	120 mL	Millia Had		
(Building B) 4	780 ml ACI	V (Fishe	= (n-line)		
lot playell and	(1.1.)	1 . 1	× (Opinio)	-	-
10x 6104511, exp	ollog), Filter	<u>æl</u> ahd	_dega_ssed_	-	
Wavelength/Inj. Volume/Flor Standard Data <u>Biluted Alcohol</u> +		A) 1 (1)		e scheet-	Char
Std Rep: Std was	anied of income a	<b>b</b>	. N TO & 100	10.0-ml	- trash, make
Std Prep: Std Was ( (Bal 24) (See p. 4.110mg - 0,060mg =	705-750 (USP Digpain 1	lot cobosoph A	djusted to : NI	3	
3	1000	mL with	N	Ar	
g. Purity Factor = 0.961 n	rg/ma for RS	Wohal)	(pH adjus	Ung solution)	and the state of t
Systom Suitzbillity R	eb;	on pl	H Meter # <u>N 1</u>	or pHT	
Systom Suitzbility A: (921 26) 4.041mg - 0.00	5 mg USP Diggator RS	D pHB	uffer Check(s)		(pH tester)
(92) Zia) 4.025 mg - 0.01	gazigenin (s	igmzs ora	3 H37846, 10/10	>	*
14.000 - 0.016 mg - 4	1033 mg CUSP OGOKIN F	(S)	100.0ml (di	lithed a	ucohol)
oried std in Vacuum Out	en I (TZW) 25 25	gauge In-Ha x	1hr/TM-7-1	rai fail	of Sule Chiteren
(2) Roomanie.		. ノ			for Deviation
(3) Reprepped System s not passing system	is suitability. See	cause it	tion of tentantion of	Digoxin	RS MAS
O spelling AEB 1/28/07 @	redried and APR I - N	lor	· · · · · · ·		
Signature/date:	1_	ewed by/date:		and the state of t	
Form: SCH007.19 Effective: 10-17-2003		And the state of t	essential des franches au se dans times aux - traps y filip des traps que mention des servicies de destito del	end-uurukkinjelemmenin kuunuuuuuuuuuun ohjeedda ,	Andrew State

01/26/2007 14:25:50

02/02/2007 11:16 FAX 314 487 6776

CELSIS LABS

Ø027/050

### Deviation and Discrepancy Report

Date of Event 1-8-07	Number: (07-007
Discrepancy Deviation	Planned Upplanned
Description/Impact of Event The Vacuum oven Current	Huis use sulla son
The hell vacuum was pulled wh	responds to 29 under x/g.
for drigona for an interior period,	entila new
Root cause: Vacuum pump oo Calibrated Vacuum is used. The USP requirement drue to the Capability of the Vacuum	and a full
NA (1-07)	GCOPY
	·
Corrective Action/Preventative Action: a Mus pump purchased Calibrates & placed into	
NA WIL-07	
See attached	
Priginator Signature/Date: Alleans 1-11-07	
Sanagement Signature Date: Lenius Min Sessie 2	411/2057
A Signature/Date: K. Jewell 1/12/07	Monthly for the state of the graph of the state of the st
sin: #CAD028,1 Eactive: 12/22/05	

JAN. 29. 2007 11:57AM

MYLAN GSO QA

NO. 5006 P. 6



101 E. Main Street, Little Falls, NJ 07424 • Ph: (973) 8901440 • Fax: (973) 890-7980.

Digoxin Tablets 0.125 mg

BATCH # 60992A

## CERTIFICATE OF ANALYSIS GENERATED FOR CUSTOMER PURPOSES ONLY

All testing has been performed in accordance with GMP and GLP and all results have been found to comply with the registered specifications.

Part of Bulk Batch # 60992A is bottled as Control # 60992A1 (PACK SIZE 100)

Manufactured Date: 11/11/06

Approved By: Segulatory Affairs

Date

Ut.7

£0:0 400m - 4 ...

\_\_JAN. 29. 2007\_11:57AM

MYLAN GSO QA

NO. 5006 P. 7

#### Actavis Totowa LLC

#### CERTIFICATE OF ANALYSIS

Product Name:

Digoxin Tablets 0.125 mg

Date of Analysis: 01/05/07

Control Number: 60992A

Exp. Date: November 2008

TEST	" RESULT	LIMIT
DESCRIPTION: Color:	Yellow	Yellow
Profile:	Round bisected tablets	Round bisected tablets
Other: Debossed	"B 145" on bisected side	"B 145" on bisected side
FRIABILITY:	0.1%	NMT 1.0%
IDENTIFICATION: (A)	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.
(B)	The Rf value of test solution corresponds to standard solution.	The Rf value of test solution corresponds to standard solution.
ASSAY: Digoxin, 0.125 mg	99.4%	90.0% - 105.0%
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity) Digoxin, 0.125 mg	1) 99.2% 6) 101.0% 2) 96.9% 7) 99.2% 3) 100.4% 8) 97.7% 4) 98.5% 9) 97.2% 5) 97.8% 10) 98.8% AVG: 98.7% RSD: 1.4%	85.0% - 115.0% RSD: NMT 6.0%
DISSOLUTION: Media: 500mL; 0.1N HCl Apparatus: I, RPM: 120 Temp: 37.0°C ± 0.5°C Time: 60 minutes	1) 102.2% 4) 99.3% 2) 99.5% 5) 99.2% 3) 102.4% 6) 102.2% Average: 100.8%	NLT 80% (Q) of the labeled amount of Digoxin is dissolved in 60 minutes.
Related Substances: Digoxigenin	0.181%	NMT 2.0%
Digoxigenin bisdigitoxoside	Not Detected	NMT 2.0%
Gitoxin	Not Detected	NMT 3.0%

Director of Quality Control

Date | 5 |

02/02/2007 11:16 FAX 314 487 8778

CELSIS LABS

@ 028/050

# Celsis | Analytical Services

## Report of Analysis

Attn. Name: Thomas Spaine

Company: UDL Laboratories, Inc.

Address: 1718 Northrock Court

City, State, Zip: Rockford, IL 61103

Sample ID#: 783544

Report Date: 02/02/2007 Received: 01/30/2007

Department: Chemistry

Page: 1 of 1

Sample: Digitek 125 mcg

Lot #: 60992A1 (Skid #7 Top) exp. 11/08

Digoxin Assay Test:

Method: Current USP and Supplements

Claim: 125mcg/tab(0.125mg/tab)

Limit: 90.0 - 110.0%

Result: Date Assayed: 1/30/2007

126 mcg/tablet (100.8%) - Conforms

Test: Dissolution

Method:Current USP and Supplements

Limit: NLT 85% in 60 min for the avg of the tablets tested

Result: Date Assayed: 1/30/2007

Component: Digitek

Stage	e 1
Sample #	% Dissolution
	97
4	98
3	98
A .	100
5	98
0	99
	98
6 Average for 6 Conforms	

Unless alternate arrangements have been made, sample will be retained for 30 days and raw data for 7 years after report date

Celsia Laboratory Group 6200 S. Lindbergh Blvd. St Louis, MO 63123 USA 7+1 314 487 6776 F+1 314 487 8991

Calsis Analytical Services represents that this is a confidential report which may be used when requested by physician and health officials, but is not to be used in any form of advertising without written permittion

Part of the Celsis International ple group of companies www.celsiz.com

	CELSTS LADS	@0297050
UDL Laboratories, Inc	Due: 02/02/2007	Sample ID#: 783544
Sample: Digitek  125 mg 125 mcg PO #: A29A3	Lot #: 60992A1 (Skid #7 Top) exp. 11/08  Desc: wht plst btl/wht lid w/tabs  Qty: 1btl = 100 tabs	Page: 1 of 5  577 Hole J Extra: NA  20% D: Log: 01/30/2007
Safety Name: No Safety Type DEA #: N/A		incorrectly entered.
Instructions: For all disintegrations report number of n	nimutes, when possible. Send all date and reports overnight	\$1,575.00
Digoxin Assay Current USP and Supplements	Results:	\$0.00 0.00 %
Claim: 125mcg/tab(0.125mg/tab)  Limit: 90.0 - 110.0%	(1,8,001)	\$1,575.00 [498]
SubDept: HPLC		Conlorms
Alert Limits: 93.31 104.71.3		does not N/A
Anc Data: (Yes) No Anc Ref: 2017	78 3544 Assay Date: 1/30/0	7
Method Instructions: NA	and the second s	New York Control of the Control of t
(Br. 179) (Claim: 0.125 mg) (Civ 2-2-0) Need: I mg (Br. 191) Spl Prep:	2072005 = 0.1056979/120 $105.697 = 105.697 = 105.6979/120$ $105.697 = 105.6979/120$ $105.697 = 105.6979/120$	= 845.574 mg of sp1 needed
345.5 mg of spl transfer BIND Added 25.0 ml (d × 30 min (TM-77 0.8-um membrane ASSZY result: 0.1259	red to 2 glass-stoppered invited according with swirling and cooled. Filtered a bilter, discarding the congress of the page 1000 mg/mg) = 1,000 mg/mg) = 1,000 mg/mg.	, 50-ml conical flask ng, schicated (son-2) portion through a first 10-ml of fittrade 25-9-49/tab

Onot needed +22 -1.107 (2) Units Acro 21.107 (3)	Wg and ARR 21/107 (4) wg arcillary ARB	2/2/07
Signature/Date: Bischeff 2/2/07	Reviewed By/Date: Christander 2 2 07	
Form: SCH007 10 Effective: 10-17-2003 Page 1 of 2	The state of the s	

02/02/2007 11:18 FAX 314 487 6776	CELSÍS LABS	2030/050
		£ 0307 030
	Due: 2/2/2007	Sample ID#: 783544
SubDepartment: HPLC	ANL#:	Page: 2 of 5
	4	RXITAL NA
Carlona HE		(D) Chromeleon Pages: 1-12A
seguence Ars D	20107-498-2	(S) Chromeleon Pages: 1-12A FSYSTEM SUIT) (Sample calc)
Analyte: Digoxin (	Digitek) tablets	ID# Reference
Method: USP 29	OL Idigoxin tal	olets) (881282-
System Identification: <u>LC-2</u>	7_	<u>24m0</u> 783543
Column: H-39 Epic e18	54 120Å 25cm x	4.2mm
S/N: 16104-14-78-51399	: guzurd column: EPIC C18.	5) SIN: 23704-
Mobile Phase: (37-13 H20-AU	V) 1480 mL Milli-C	3.2×15mm 2 H2O
(Bld-B) + 520 mL A	ion (Fisher Optima	lot 064511 NA /
exp oilos). Filtered a	•	241/07
NA	<u> </u>	
Wavelength/Inj. Volume/Flow Rate:	218-nm/5aul/3	on Unin
Standard Data		
Std Prep: USP Digoxin RS 1	lot 008096)	. /
(+711 216) 4.016= 0.012mg = 4.004m Std (oncontration = 4.004mg	ng > 100.0ml (diluter	ANCILLARY
Std Concentration = 4.00 mg/ Purity Factor: 0.9/el mg/mg for	100.0ml=0.04004mg/ml	E SEE Jankson Comp V stall in
	pH Adjuste	d to: NA
System Suitability Rep: (usp Di	govin RS? Digoxygenin lith	NA
Digoxygenin (Sigma, 028H37846)	, 10110)	(pH adjusting solution)
H.098=0.001mg = 4.077mg	> 100.0mL on pH Mete	r# NA or pHT# NA (pH tester)
4.017 mg - 0.002 mg = 4.009 mg	(Liluted OH) pH Buffer C	Check(s)
NOTE: SEE PHORT OF REIZI	32-24mo for std dryi	ng and diluted alcohol prep
•	•	
(Dnot needed AEB 21,107 (2) wordin	m AEB 42 by	
Signature/date: Bischoff 2	2/2 Reviewed by/date:	vaslaugh z/2/07
Form: SCH007.10 Effective: 10-17-2003		C. Commission from the commission
Page 2 of 2		

01/30/2007 12:23:03

CELSIS LABS

Ø031/050

		Chr	omatography	Report	*		
Sequ	ience Title:	Digoxin Assay			Total Samples:	11	
Sequ	Jence Name:	020107-498-2b	Sample No.: 1				
Syste	em ID:	LC-22			•		
Proc	essing Date/Time:	02/01/07 14:28:51					
Crea	ted by:	Anna Bischoff					
Loca	tion:	ServerData	2007\1 JAN THRU	MARCH\498			
	oration						
No.	Peak Name		Cal.Mode	Cal.Type	#Points	Corr.Coeff.	
Peak	Analysis						
No.	Peak Name		Resolution	Tailing	Plates	K'	
L			(USP)		(USP)		
Syst	em Suitability	•		-			
				- Andre in Communication of the Annual Communication of the Communicatio			
			n.a.	n.a.	n.a.	n.a.	
No.	Name						
			UV VIS 1	UV VIS 1	UV VIS 1	UV VIS 1	
7	Standard 1		n.a.	9.27425808	n.a.	n.a.	
10	Standard 2		n,a,	9.28040090	n a l	n,a,	
		%RSD	#DIV/0!	0,047	#DIV/0I	#DIV/0	
_	rst Signature/Date: teview/Date:	Anna Bisco Chemis			Al	NCILLARY	

added p iA to show system suitability.

AEB 2/107

6,70 SP2s Build 1971 Version Number 2,2

Page 1 of 12

current time: 2:29 PM

CELSIS LABS

@032/050

Chromatography Report

Sequence Title:

Digoxin Assay

Total Samples: 11

Sequence Name:

020107-498-2

System ID:

LC-22

Processing Date/Time: 02/01/07 14:20:34

Sample No.: 11

Created by:

Anna Bischoff

Location:

ServerData

2007/1 JAN THRU MARCH/498

Calib	ration				
No.	Peak Name	Cal.Mode	Cal.Type	#Points	Corr.Coeff.
]					%
1	Digozygenin	Total	Lin	5	99.997
2	Digoxin	Total	Lin	5	99.990

Peak Analysis

reak	Allalysis				
No.	Peak Name	Resolution	Tailing	Plates	K,
		(USP)		(USP)	
. 1_	Digoxygenin	13.49	2,46	1167	n.ø.
2	Digoxin	n.a.	1.96	1607	n.a.

System Suitability

		Digaxygenin	Digozin	n.a.	n.a.
No.	Name			1011500	41124111
		UV VIS 1	UV VIS 1	UV VIS 1	UV VIS 1
2	System Sullability 1	19.61372095	9.06532399	n.a.	n,a.
3	System Suitability 2	19.56334623	9,04740426	n.a.	n.a.
4	System Suitability 3	19,58746710	8.97129354	п.в.	n.a.
5	System Sultability 4	19,70433584	8.92523679	n.a.	n,a.
6	System Suitability 5	19.54114496	8,99209405	na.	n a.
	%RSD	0,323	0.633	#DIV/0!	#DIV/0!

Analyst Signature/Date:

Chemist

ANCILLARY

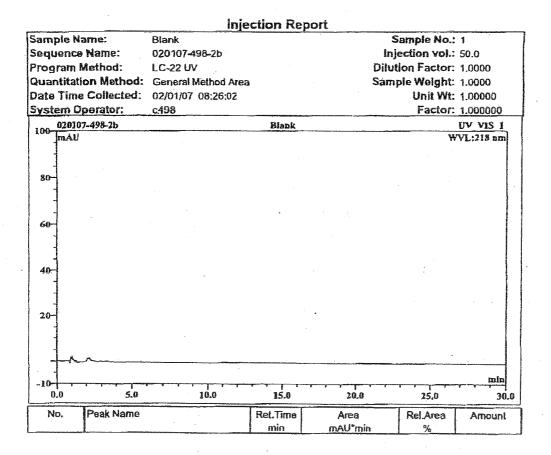
QC Review/Date:

6.70 SP2s Build 1871 Version Number 2.2

current date:2/1/2007 current time: 2:22 PM

CELSIS LABS

Ø033/050



**ANCILLARY** 

Chris Vanda 2/2/07

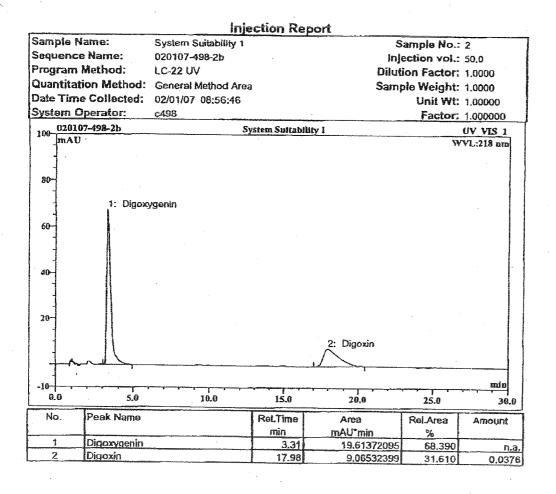
6.70 SP2a Build 1871 Version Number 2.2

Page 2 of 12

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CELSIS LABS

Ø034/050



**ANCILLARY** 

Christengle 2/2/07

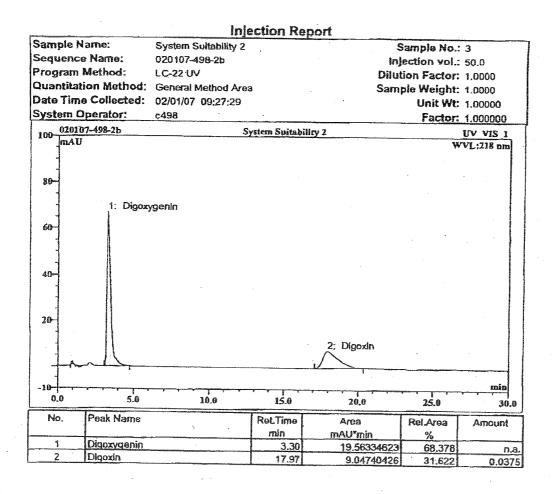
6,70 SP2a Build 1871 Version Number 2.2

Page 3 of 12

current date:2/1/2007 current time: 2:29 PM

CELSIS LABS

@035/050



**ANCILLARY** 

Chris Vangle 2/2/07

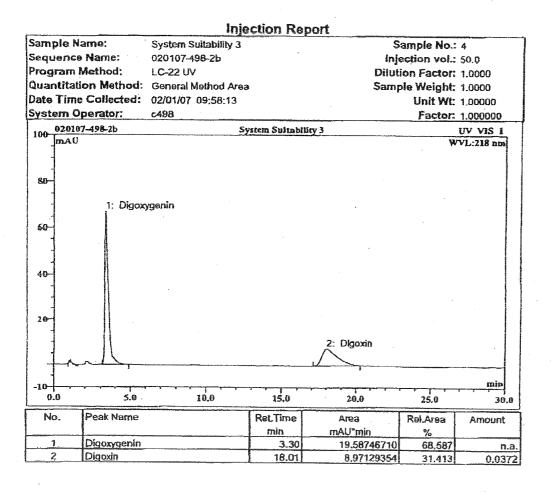
6,70 SP2a Bulld 1871 Version Number 2.2

Page 4 of 12

current date:2/1/2007 current time: 2:29 PM

CELSIS LABS

Ø036/050



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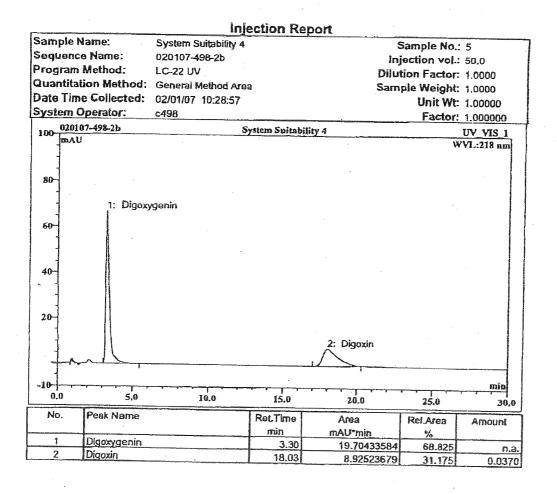
6.70 SP2a Build 1871 Version Number 2.2

Page 5 of 12

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CELSIS LABS

Ø 037/050



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Chris Vancher 2/2/07

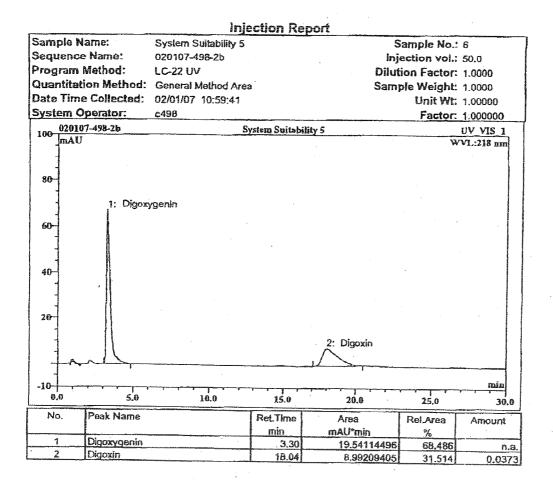
6.70 SP2a Build 1971 Version Number 2.2

Page 6 of 12

current date:2/1/2007

CELSIS LABS

Ø 038/050



ANCILLARY

Chris Vangle 2/2/07

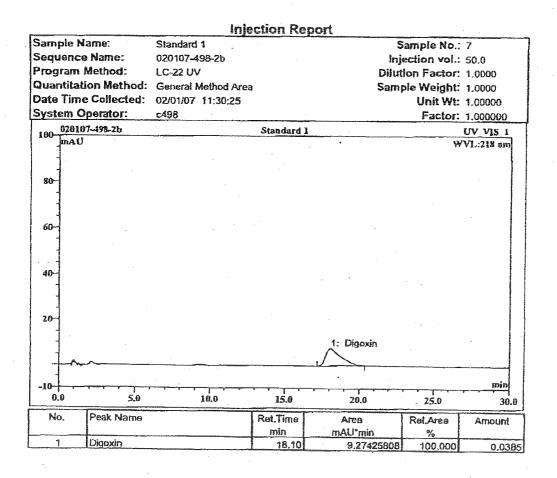
6.70 SP2a Build 1871 Version Number 2.2

Page 7 of 12

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CELSIS LABS

Ø 039/050



**ANCILLARY** 

Chris Vargue 2/2/07

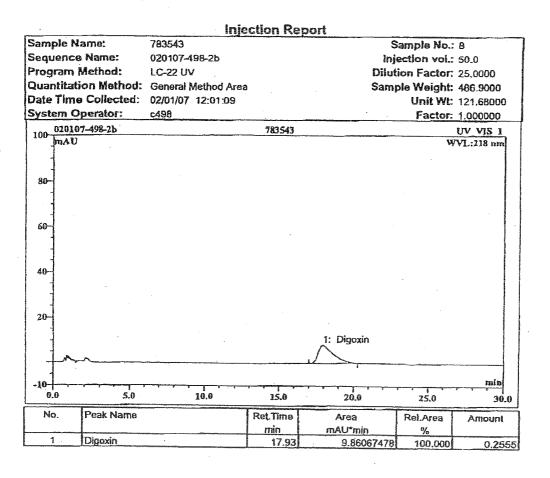
6.70 SP2a Build 1871 Version Number 2.2

Page 8 of 12

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CELSIS LABS

Ø 040/050



**ANCILLARY** 

ChrisVaugh 2/2/07

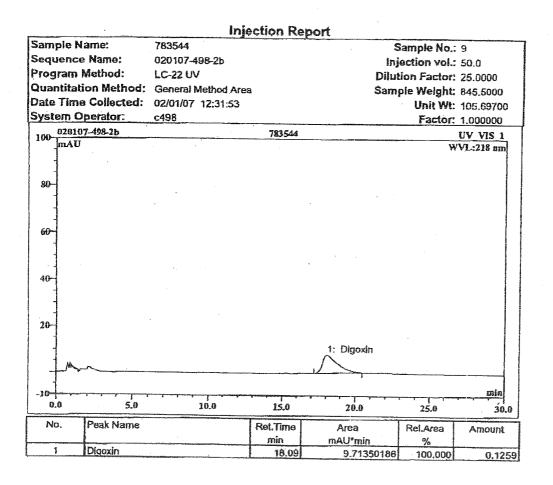
6.70 SP2a Build 1871 Version Number 2.2

Page 9 of 12

current date:2/1/2007 current ilme: 2:29 PM 02/02/2007 11:20 FAX 314 487 6776 02/02/2007 11:19 FAX 314 487 6776

CELSIS LABS CELSIS LABS

② 042/050 ② 041/050



**ANCILLARY** 

Chris Vargh\_ 2/2/07

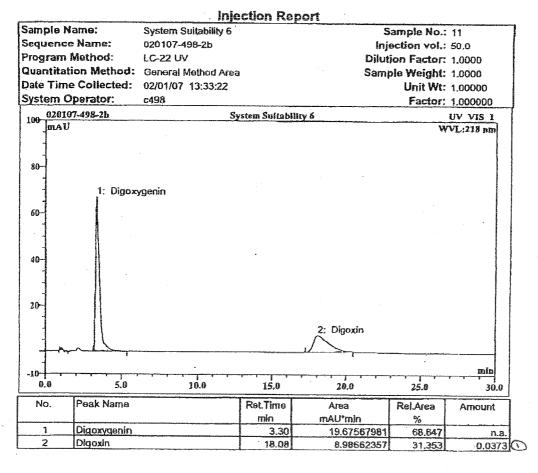
6.70 SP2a Build 1871 Version Number 2.2

Page 10 of 12

current date:2/1/2007 current dme: 2:29 PM

CELSIS LABS

Ø043/050



Othis value calcid as a spl, but not used in any sample calculation. AEB 2/2/07

ANCILLARY

Christiangle 2/2/07.

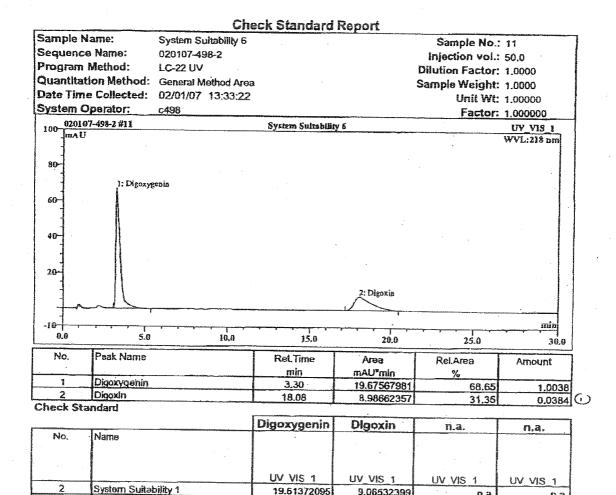
added p 12A to show system git.

6.70 SP2a Build 1871 Version Number 2.2

Page 12 of 12

CELSIS LABS

Ø044/050



11 System Suitability 6	19,67567981	8.98662357	n.a.	n.a.
%RSD	0.327	0.570	#DIV/0!	#DIV/0!
				America de la constante de la
Othis value used	d to coulc. eve	tem enel	14 125 M	a f.
L	-	TON SUMA	DI PANICE	ar useci
to calc. spl.	ZUMT. ABB 3	42/07		

9.06532399

9.04740426

8.97129354

8.92523679

8.99209405

19.61372095

19.56334623

19.58746710

19.70433584

19.54114496

n.a

n.a.

n.a.

n.a.

n.a.

6.70 SP2a Build 1871 Version Number 2.2

3

4

5

6

System Suitability 2

System Suitability 3

System Suitability 4

System Suitability 5

System Suitability 6

added page AEB 2/1/07

current date:2/1/2007 current time: 2:35 PM

n.a.

n.a.

n.a.

n.a.

n.a.

CELSIS LABS

Ø045/050

JDL Laboratories, Inc	Du	÷ 02/02/2007	Sample ID#:	783544
Sample: Digitek  125 tog PO #: A29A3	Desc	60992A1 (Skid #7 Top) exp. 11/08 wht plst bil /wht lid w/tabs  1bil = 100 tabs		Page: 3 of 5 Extra: N/A Log: 01/30/2007
Safety Name: No Safety Type DEA #: N/A		Corrections: Sample name and L	init 01-31-0	7/m7
Instructions: For all disintegrations report number of	f minutes, when p	ossible. Send all data and reports overnight	**************************************	\$3,810,00
Dissolution Current USP and Supplements	Results:	400	angalan ana anjan garangan angan	\$0.00 0.00 5
Claim: n/a  Limit: NLT 60% is 30 min & NLT 85% in  60 min to  SubDept: Dissolution	er sei anamyna von yffillifanninin anafhrining sings	See Belo	W	\$3,810.00 4,80 conferens
Alert Limits: N/A	Parametild &			does not NA
Anc Data: Yes No Anc Ref: 783	51.7	Assay Date: 01-30-0		

Stage 1 Results					
Sample No.	% Dissolution				
1	97				
2	98				
3	98				
4	100				
5	98				
6	99				
Average for 6	98				

	% Dissolution (x)	Response (4)
1.0mL	19-362228	72
20mL	38.724456	147
3.0mL	58.086684	235
4-0 mL	77.44 8912	309
5.0mL	96.81114	368
CORR.	0.997902893	% bissolution from 800 curve.

USP-29 ONLINE, DIGOXIN TABLETS.

# FACTOR-

CORR. COEF = 0.997902893 Sample % Dissolution from STD Curve.

Signature/date: Huutity /01-31-07 Reviewed by/date: Chris Vaugh 2/2/07

Form: SCH004.8 Ellective: 08-09-2002 Page 1 of 3

01/30/2007 12:26:29

		Ove: 2/2/2007	Sa	mple ID#: 783544
SubDep	partment: Dissolution	A	NL #: 480	Page: 4 of 5 Extra: N/A
U1-31	O/		The state of the s	BARY: N/A
	Checklist Procedures fo	r USP Apparatus (	OR II (circle on	<u>e)</u>
0 000 0 ==	ation ID to Told Vision Told V		· · · · · · · · · · · · · · · · · · ·	
	atus ID#:	mt lime:	7 mer #:	4-24
Mediui	m: 0.1 N HCl	, ,	·	
	58ml Hel (fish w 060506)		0 L H2D. Luca	ted a degastical
pH: (II	F APPLICABLE): pH Tester ID: N/		•	
	Buffer Set Value: N/			Value: N/A
	Buffer Manufacturer, Lot# a	and Expiration Date: _	A/u	- Maria de la companya del companya de la companya del companya de la companya de
1.	Inspect all paddles or baskets, shafts, and and check the verticality shaft.	vessels for cleanliness Pass ⇔	s, deformations, burrs,	or other defects,
2.	Check the adjustment of each assembly so	that each paddle or b	asket is	
	2.5 cm or 4.5 cm (circle one	H6-1		
	above the inner floor of the vessel. The tole to the correct height. All are within tolerand	erance is 2 mm. Each	shaft is marked so it o	an be returned
3.	Measure temperature of the water bath. Th	ne tolerance is 37° ± 0,	5°C. Pass ⇒ ✓	
	Temperature: 37-0	°C Thermo	neter#: <u>T-122.0</u>	
4.	Select the gear drive or adjust the speed co Turn on the motor drive. Measure the shaft counting device. Allow the machine to run deviation from the speed specified in the method is ± 2 rpm.	resolutions per minut	e by manual count or t	v a revolution.
	Speed (rpm):	-		
5.	Inspect the shafts for straightness. Instal wobble by placing a runout gauge against (0.04 in.). All within tolerance. ⇒ ∨	each shaft just above	engage clutches, and the paddle or baskel	measure the amount . The tolerance is 1 m
	Wobble Gauge ID: しょうし	·		•
	1.0.003 2.0004 3.0	9.001 4.0	<u>005</u> 5, <u>0.00</u>	06 6.0005
5.	Measure the temperature of the medium in a Thermometer #: $T-122$ $D$	each dissolution vesse		
	1.37.0 2.37.0 3.3	37.0 4.3	5.36.9	6. 36-9
Signatu	ire/Date: 1/ le hare 1/30	Reviewed B	y/Date: Chris Vaya	ala la 3

01/30/2007 12:26:29

CELSIS LABS

Ø047/050

#### Additional Analytical Worksheet

Glassware rinsed with HCI (fisher, Lot # 060506, 10-09), DI Water and Alcohol (Apper, Lot # 0411668, 3-10) and earefully dried.

STANDARD = DIGOXIN (USP\_STD, lot # 008096, 0.961 mg/per mg)

SEE R81282 24 ma pgch of 7 for drying.

5.065 mg
0.028 mg

5.037 mg STD -> closed tightly and soucd.

STOCK STD = 5.037 mg Digorin STD \_\_\_\_ 100.0 ml 4IN 5 ALCOHOL

01-31-07

WORKING STD =

5.0 ml STOCK STD \_\_\_ SO.0 ml 4 IN 5 ALCOHOL

# 4 IN 5 ALCOHOL =

160 mL Ethyl Alcohol (Apper, Lot # 041166B, 3-10) -> 200.0 mL WATER.
ASCORBIC ACID METHANOL SOLUTION:

SEE 783542 PAGE 5 B.

HYDROGEN PEROXIDE-METHANOL SOLUTION =

STOCK = 2.0 ml Hydrogen Peroxide (Sigma, 095K3774, 5-07) -100.0 ml Methanol (Sigma, 00561HE, 1-08) WORKING = 2.0 ml H2O2 - Methanol Stock -> 100.0 ml Methanol

### STANDARD SCLUTIONS -

1.0 ml (20%), 2.0 ml (40%), 3.0 ml (60%), 4.0 ml (80%), 5.0 ml (100%), 5.0 ml (100%), 5.0 ml (100%)

1 TABLET - 500 ml medium.
filtered with 045 micron Nylon filter.

personal control of the control of t							
1			The state of the s	The second secon			-
ł .		2	g .		7 1	*	
Signature/Date:	17 .416	/	I 100-	AP 7	()	i	
1	1 4 4 4 4 7 7 7 4	/ ni	I Designed the Color	. 11 11	11 (	;	
E CHEST INTEREST OF THE COL	1 B. S.	/ 01= 31 13/	I DEALEMARU DANIMIR	/ / - //	12 1	1	
	7-7-10-30-5-6-6-7	, , , , , , , , , , , , , , , , , , , ,	i i i i i i i i i i i i i i i i i i i	" / les Ver	. Ui - ¬ i ->	E and and a	
		• ,	Reviewed By/Date:	1 8 6 10 10 10 10 10 10	321 A 2 1 /	103 2	
	Bar)	The state of the s	the state of the s	The second secon	A Contract Contract	100	
					Annual Contraction of the Contra		***************************************
	2.7				1		
	· · · · · · · · · · · · · · · · · · ·			3	8		
C CC1 (00 4 0					. ?		
Form: SCH004.8	•				<b>4.8</b>		

Form: SCH004.8 Effective: 08-09-2002 Page 3 of 3

01/30/2007 12:26:29

CELSIS LABS

@048/050

UDL Laboratories, Inc	Due:	2/2/2007	Sample ID#: 783544
Sub Dept: Dissolution		ANL #: 480	Page: 5 A

21-31-07

## Additional Analytical Worksheet

Prepared 1.0 mL Medium as Blank, 1.0 mL cach Standar Solutions, 1.0 mL each Semple Solutions. Also prep. dublication of all solutions. Added 1.0 mL Ascorbic Acid-Methanol Solution and swirled. Added 5.0 mL HCI (Fisher, Lot # 060506, 10-09) and swirled. Added 1.0 mL Hydrogen Peroxide-Methanol Working Solution and swirled, capped allowed to sit 2 hours, TM-54.

FMR-I

Fluorescence

=485 nm

SPAN = MAX

Excitation Wavelength = 372 nm.

Excitation filter = NB360

Emission filter = SC415

FMR-I Zeroed with Blank.

2-crord with Blo	nk	Duplication	Average
STN 20 %	69	74	72
STD 40 %	149	145	147
STO 60 %	236	234	235
STD 80 %	305	313	309
STD 100 %	374	362	368

·		Duplication	Average
Sample VI	.374	382	378
Sample V2	378	384	381
Sample V3	<i>3</i> 83	377	380
Sample V4	388	394	391
Sample V5	384	381	383
Sample V6	389	<i>3</i> 80	385
sro 100%	376	368	372

N/A 01-31-07 MY

Signature/Date: Hatty / 01-31-07 Reviewed By/Date: Chaskry 2. 7 07

Formit: SCHC001,4 Effective: 04-02-2004 Page 1 of 1

1/31/2007 4:36:58PM

CELSIS LABS

Ø048/050

UDL Laboratories, Inc Due: 2/2/2007 Sample ID#: 783542 Sub Dept: Dissolution ANL#: Page: 5 B 480 01-31-07 N/A Additional Analytical Worksheet bigoxin (usp-stb, Lot = 008096, 0.961 mg/pcr mg) [C] [C] SEE R81282 24 mo. for STO drying and Stock STO. (Page 4 of 7) STOCK = Bal = 26 5.065 mg - 0.028 mg = 5.037 mg STD - 100.0 mL 4 IN 5 ALCOHOL 10.0 ml STOCK STD \_ 50.0 ml 4 IN 5 ALCOHOL 4 IN 5 ALCOHOL = 160 ml Ethyl Alcohol (Acper, Lot # 041166B, 3-10) -, 200.0 ml H20 ASCERBIC ACID-METHANOL SELUTION = 200.00 mg Ascorbic Acid (Sigma, 063 k1082, 8-10) - 100.0 mL Methanol (Sigma, 00561HE, 1-08) HYDROGEN PEROXIDE - METHANOL SOLUTION = STOCK = 2.0 ml Hydrogen Peroxide (Sigma, 095K3774,5-07) - 100.0 mL Methanol (Sigma, CO56/HE, 1-08) WORKING = 2.0 ml H202-Methanol Stock \_ 100.0 ml Methanol STANDARD SOLUTIONS -1.0 ml (20%), 2.0 ml (40%), 3.0 ml (60%), 4.0 ml (80%), 5.0 ml (100.0 %)
-, 100.0 ml MEDIUM. See page 5A to fallow FMRI reading and prep. ANCILLARY N/A 01-31-07 ANCILLARY Signature/Date: 46 01-31-07 Reviewed By/Date: // Form#: SCHC001.4 Effortive: 04-02-2004 Page 1 of 1

1/31/2007 \$:14:51AM

	Interval: 24 Month Due: 2/12/2007	Sample ID#: R81282
nple: Digitek (Digozia)	Lot#: 5All3 (Mfg. Amide/Bertek Vendor # 427)	Al) ANL#:
125 mcg (0.125 mg) Tabl	lets, USP Desc: UVI Package	498
Date: 1/29/07	SubDepartment: HPLC	Page: 4 of 7 Extra:
	Chromele	on Pages:
		•
Analyte: Digoy	in (Digitek) tablets	ID# Reference
(J)	OL 29	Management and the second and the se
System Identification:		- EPPOS
Column:		
Mobile Phase: (37:12	5 Hzo: ACN) 2220 mz Millio H	20
(Building B) -	+ 780 mz ACN (Fisher Optima)	
	oilor). Filtered and degasser	
		l
silvted Akahol +	500-ML Ethyl Alcohol (AADER, OHDZO 500-ML purified Water (B-12) to 2	QA, OYON Flask, m
ailused Alcohol t	and mixed , while water (B-12) to 2 ,	000.0-ml flask, m
at Prep: std was Bal 210) (see p	and mixed water (B-12) to 2 1 and mixed to 5°C × 1 hour. To 5-7 (USP Digoxin lot openabH Adjusted to:	NA Flask, m
Ad Prep: std was Bal 2107 (see p. 1.110mg - 0.060mg =	and mixed  Avied at 105°C × 1 hour  Tos I (USP Digoxin lot opposite H Adjusted to:  H. 050mg > 100.0-ml with  (diluted a)(choil) (pH)	NA
Alcohol  Hd Prep: std was Bal 210) (see p. 1.110mg - 0.060mg =  Ority Factor = 0.961  Storm Suitzbility F	and mixed  Aried at 105 c × 1 hour  Tos TO (USP Digoxin let coeras) H Adjusted to:  H.050mg > 100.0-ml with  (diluted 2)(choi) (pH)  mg/mg for RS  on pH Meter #  Depring USP Digoxin RS  pH Buffer Check(s)	NA  NA  OUT OF PHT#  NA  (pH tester)
Ad Prep: std was Bal 210) (see p. 1110mg - 0.060mg = Pority Factor = 0.961 Potern Suitability F 121 210) 4.041mg - 0.0 Pal 210) 4.025mg - 0.0	and mixed  Aried at 105 c × 1 hour  Tos I (USP Digoxin lot obenop) H Adjusted to:  H. 050mg > 100.0-mL with  (diluted alcohol) (pH:  mg/mg for RS  on pH Meter #  Digoxidenin (Sigma, 018 H57846, 10	NA  NA  OUT OF PHT#  NA  (pH tester)
Ad Prep: std was Bal 210) (see p. 1.110mg - 0.060mg = Pority Factor = 0.961 Hotom Suitzbility F Ma 210) 4.041mg - 0.0 Ma 210) 4.025mg - 0.0 May 1005mg - 0.0 Ma	and mixed  and mixed  dried at 105 °C × 1 hour  the obling > 100.0-ml with  (diluted alcohol)  my/my for RS  on pH Meter #  ph Buffer Check(s)  claim Digoxigenin (Sigma, o 18 H57846, 10  H.033 mg(USP Digoxin RS)  H.009 mg(Digoxin RS)  H.009 mg(Digoxin RS)	NA  NA  NA  Adjusting solution)  NA or pHT# NA  (pH tester)  (no)  diluted alcohol)
Ad Prep: std was BZJ 2107 (see p. 110mg - 0.060mg =  Ority Factor = 0.961  Std 210) 4.041mg - 0.0  Del 210) 4.025mg - 0.0  OHIMG- 0.005mg =  OS mg-0.016mg =  ed Std in Vacuum C	and mixed  Aried at 105 °C × 1 hour  Tof I (USP Digoxin bet objects) H Adjusted to:  H. 050mg > 100.0-ml with  (diluted Diconin RS)  on pH Meter #  Dep:  Offing Digoxin RS)  PH Buffer Check(s)  H. 033 mg(USP Digoxin RS)  H. 009 mg(Digoxin RS)  H. 009 mg(Digoxin RS)  Nen I (T244) H 25 In-Hg × 1 hr (TM-	NA  NA  NA  OUD.O. ML Flask, me  NA  Oliviting solution)  NA or pHT#  (pH tester)  (io)  diluted alcohol)  it) at iot'c for Device.
Ad Prep: std was BZJ 2107 (see p. 110mg - 0.060mg =  Ority Factor = 0.961  Std 210) 4.041mg - 0.0  Del 210) 4.025mg - 0.0  OHIMG- 0.005mg =  OS mg-0.016mg =  ed Std in Vacuum C	and mixed  Aried at 105 °C × 1 hour  Tof I (USP Digoxin bet objects) H Adjusted to:  H. 050mg > 100.0-ml with  (diluted Diconin RS)  on pH Meter #  Dep:  Offing Digoxin RS)  PH Buffer Check(s)  H. 033 mg(USP Digoxin RS)  H. 009 mg(Digoxin RS)  H. 009 mg(Digoxin RS)  Nen I (T244) H 25 In-Hg × 1 hr (TM-	NA  NA  NA  OUD.O. ML Flask, me  NA  Oliviting solution)  NA or pHT#  (pH tester)  (io)  diluted alcohol)  it) at iot'c for Device.
Hd Prep: Std was Bal 220) (see p. 1.110mg - 0.060mg = Pority Factor = 0.961 yetern Suitzbility F 221 220) 4.041mg - 0.0 221 220) 4.025mg - 0.0 041mg-0.000mg = 1.000mg - 0.01eng - ed 5td in Vacuum C 31.07 Reprepped System not passing syste	and mixed  and mixed  dried at 105 °C × 1 hour  the obling > 100.0-ml with  (diluted alcohol)  my/my for RS  on pH Meter #  ph Buffer Check(s)  claim Digoxigenin (Sigma, o 18 H57846, 10  H.033 mg(USP Digoxin RS)  H.009 mg(Digoxin RS)  H.009 mg(Digoxin RS)	NA  NA  NA  OUD.O. ML Flask, me  NA  Oliviting solution)  NA or pHT#  (pH tester)  (io)  diluted alcohol)  it) at iot'c for Device.

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